

EXHIBIT 32

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced)
Air Warming Products)
Liability Litigation:)
)
) MDL No.: 15-2666
) (JNE/FLN)
This Document Relates To:)
)
All Actions.)
_____)

VIDEOTAPED DEPOSITION OF WILLIAM R. JARVIS, M.D.
San Francisco, California
Tuesday, July 25, 2017

BY: HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR
CSR LICENSE NO. 12885
JOB NO. 124789

<p style="text-align: right;">Page 2</p> <p>1 July 25, 2017 2 9:00 a.m. 3 4 Videotaped deposition of WILLIAM R. 5 JARVIS, M.D., held at One Market Plaza, 6 Spear Tower, San Francisco, California, 7 before Heidi Belton, a Certified Shorthand 8 Reporter, Registered Professional 9 Reporter, Certified Realtime Reporter, 10 California Certified Realtime Reporter, 11 Certified LiveNote Reporter, and NCRA 12 Realtime Systems Administrator. 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: 2 For the Plaintiff: 3 LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY 4 & PROCTOR 5 By: Ben Gordon, Attorney at Law 6 316 South Baylen Street 7 Pensacola, Florida 32591 8 9 10 - AND - 11 PENDLEY, BAUDIN & COFFIN 12 By: Christopher Coffin, Attorney at Law 13 24110 Eden Street 14 Plaquemine, Louisiana 70765 15 16 17 - AND - 18 KENNEDY HODGES 19 By: Gabriel Assaad, Attorney at Law 20 4409 Montrose Boulevard 21 Houston, Texas 77006 22 23 24 25 ///</p>
<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES (Continued): 2 3 For Defendants: 4 BLACKWELL BURKE 5 By: Corey Gordon, Attorney at Law 6 431 South Seventh Street 7 Minneapolis, Minnesota 55415 8 9 10 11 Also Present: Mordecai Boone, in-house counsel for 12 3M; Sean McGrath, videographer. 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 5</p> <p>1 SAN FRANCISCO, CALIFORNIA 2 TUESDAY, JULY 25, 2017 3 9:00 a.m. 4 THE VIDEOGRAPHER: Good morning. This is 5 the start of file number 1, Volume I of the 6 videotaped deposition of Dr. William Jarvis, in the 7 matter In re: Bair Hugger Forced Air Warming 8 Products Liability Litigation in the United States 9 District Court, District of Minnesota. MDL number 10 15-2666 (JNE/FLN). 11 This deposition is being held at 1 Market 12 Plaza, Spear Tower, San Francisco, California on 13 July 25, 2017, approximately 9:00 a.m. My name is 14 Sean McGrath, from TSG Reporting, Incorporated and 15 I'm a legal video specialist. The court reporter is 16 Heidi Belton in association with TSG Reporting. 17 Would counsel please introduce yourselves, 18 starting with the questioning attorney. 19 MR. C. GORDON: Corey Gordon, Blackwell 20 Burke, on behalf of defendants. 21 MR. B. GORDON: Ben Gordon, on behalf of 22 plaintiffs. 23 MR. COFFIN: Chris Coffin, Pendley, Baudin 24 & Coffin, on behalf of plaintiffs. 25 MR. ASSAAD: Gabrielle Assaad, on behalf</p>

1 of plaintiffs.

2 THE VIDEOGRAPHER: Will the court reporter
3 please swear in the witness and we can proceed.

4 (Whereupon, the witness, WILLIAM JARVIS, M.D.,
5 having been duly sworn, testified as follows:)

6 EXAMINATION

7 BY MR. C. GORDON:

8 Q. Good morning, Dr. Jarvis.

9 A. Good morning.

10 Q. We met briefly before. I'm Corey Gordon.
11 I represent 3M in this litigation.

12 My understanding is you have been hired by
13 the plaintiffs in the multi-district litigation
14 involving Bair Hugger to offer an expert report; is
15 that correct?

16 A. Correct.

17 (Exhibit 1 marked.)

18 BY MR. C. GORDON:

19 Q. I'd like to show you what I've marked as
20 Jarvis Exhibit 1 and ask you to confirm that that is
21 a copy of your expert report.

22 A. Looks like it.

23 Q. Okay. And you want to keep that in front
24 of you because we'll refer back to that from time to
25 time.

1 Now, this is -- it doesn't appear to be
2 dated, but my understanding was that you would have
3 signed this or -- that this became your final report
4 somewhere around March 31, 2017; is that correct?

5 A. I believe that's correct.

6 Q. And on this Exhibit 1, starting at page --
7 well, I guess Attachment A. I'm sorry. That is
8 your curriculum vitae; is that right?

9 A. Yes, sir.

10 Q. And is that -- is that essentially
11 current? Is there anything that's changed since the
12 end of March that -- of note?

13 A. No.

14 Q. Okay. And in addition there's a -- I'm
15 looking for an Attachment B. That would be the list
16 of lawsuits in which you've given expert testimony
17 in the past four years. That's -- I think starts on
18 page 32 at the end. Is that -- is it correct?

19 A. Yes.

20 Q. And again since March 31, 2017, any
21 additions to this?

22 A. I believe there is [sic] two depositions.

23 Q. Do you remember the names of the cases or
24 just generally what they were about?

25 A. Both were methicillin-resistant

1 Staphylococcus aureus infections.

2 Q. Were you offering expert opinions on
3 behalf of the plaintiffs in those cases?

4 A. Yes.

5 Q. Were they product liability cases medical
6 malpractice cases? How --

7 A. Medical malpractice.

8 MR. C. GORDON: We'll come back to your
9 report. But I just want to get some housekeeping
10 stuff out of the way.

11 (Exhibit 2 marked.)

12 BY MR. C. GORDON:

13 Q. Now the -- let me show you what's been
14 marked as Exhibit 2 which is a set of invoices. I
15 will just go through them. These were provided to
16 me by Mr. Ben Gordon and Exhibit 2 should contain
17 invoices from April 13, 2016; May 11, 2016; May 21,
18 2016; August 4, 2016; December 28, 2016; March 18,
19 2017; and March 23, 2017?

20 A. Yes, sir.

21 Q. Okay. Let's start with the beginning.
22 Is -- would the April 13, 2016 be your -- the very
23 first invoice for any work you've done in connection
24 with the Bair Hugger litigation?

25 A. I believe that's correct.

1 Q. And this meeting or this invoice reflects
2 a meeting in Atlanta, Georgia on April 11 and 12 of
3 2016; is that correct?

4 A. That's correct.

5 Q. So that was your very first touch point,
6 if you will, with this litigation?

7 A. I'm not sure what you mean by "touch
8 point."

9 Q. Obviously you had --

10 A. That was the first meeting --

11 Q. Yes --

12 A. -- but we had conversations before this.

13 Q. When you say "we," what -- with whom did
14 you have conversations prior to April 11 and 12,
15 2016?

16 A. I couldn't tell you everyone, but
17 certainly Mr. Gordon.

18 Q. Mr. Ben Gordon?

19 A. Yes.

20 MR. B. GORDON: Not Mr. Corey Gordon?

21 MR. C. GORDON: It's going to confuse the
22 heck out of me if --

23 THE WITNESS: Mr. Ben Gordon.

24 MR. C. GORDON: The good-looking one. Let
25 the record reflect the good looking one -- I don't

<p style="text-align: right;">Page 10</p> <p>1 even know how to describe that sound.</p> <p>2 MR. ASSAAD: I'm still confused. Can</p> <p>3 you --</p> <p>4 MR. C. GORDON: I will stipulate.</p> <p>5 MR. B. GORDON: You're muddying up the</p> <p>6 record.</p> <p>7 MR. C. GORDON: I think we'll all</p> <p>8 stipulate Mr. Assaad.</p> <p>9 Q. So was -- is it Mr. Ben Gordon and his law</p> <p>10 firm that initially retained you in this matter?</p> <p>11 A. Correct.</p> <p>12 Q. Do you have any retention agreements with</p> <p>13 any of the other plaintiffs' law firms that are</p> <p>14 involved in this litigation?</p> <p>15 A. No.</p> <p>16 Q. So at some point Mr. Ben Gordon or</p> <p>17 somebody from his law firm got in touch with you</p> <p>18 about this litigation; is that right?</p> <p>19 A. Correct.</p> <p>20 Q. Had you had any relationship with Mr. Ben</p> <p>21 Gordon or his law firm before you had done any work</p> <p>22 for them?</p> <p>23 A. No.</p> <p>24 Q. Do you know how they were -- how they</p> <p>25 found you or how they got to you?</p>	<p style="text-align: right;">Page 11</p> <p>1 MR. B. GORDON: Object to the -- I object</p> <p>2 to the extent it calls for privileged work product</p> <p>3 information. If there's anything that I told you</p> <p>4 about that, you don't have to say it.</p> <p>5 THE WITNESS: I believe the contact was</p> <p>6 through another intermediary asking me if I would be</p> <p>7 interested in reviewing materials on the Bair</p> <p>8 Hugger. And I said yes. And then next was a</p> <p>9 conversation with Mr. Ben Gordon.</p> <p>10 BY MR. C. GORDON:</p> <p>11 Q. Was that intermediary a lawyer?</p> <p>12 A. Actually, no.</p> <p>13 Q. Okay. Then who was that?</p> <p>14 A. I can't tell you. It was a woman in</p> <p>15 Washington DC. And I can't tell you her name.</p> <p>16 Q. Was she a physician?</p> <p>17 A. I believe she was an epidemiologist.</p> <p>18 Q. Was she a government employee?</p> <p>19 A. I don't believe so.</p> <p>20 Q. Do you know what her involvement with the</p> <p>21 Bair Hugger litigation had been that caused her to</p> <p>22 be the intermediary?</p> <p>23 A. No.</p> <p>24 Q. What did she tell you about the matter in</p> <p>25 that first communication?</p>
<p style="text-align: right;">Page 12</p> <p>1 A. I am not absolutely sure. I believe we</p> <p>2 had a phone call and she just asked me if I would be</p> <p>3 willing to review materials related to the Bair</p> <p>4 Hugger.</p> <p>5 Q. Had you had some relationship with this</p> <p>6 person before? Did she just contact you out of the</p> <p>7 blue?</p> <p>8 A. I can't remember if -- she had contacted</p> <p>9 me I believe before that she did epidemiologic</p> <p>10 studies. And she contacted me because of my</p> <p>11 expertise in epidemiology and whether I would be</p> <p>12 interested in working with her.</p> <p>13 Q. So after that, your next communication was</p> <p>14 with lawyers from -- or even Mr. Ben Gordon or</p> <p>15 lawyers within his firm?</p> <p>16 A. Correct.</p> <p>17 Q. The next invoice is from May 11, 2016.</p> <p>18 And that reflects a meeting in Atlanta, Georgia on</p> <p>19 May 9 through 10; is that right?</p> <p>20 A. Correct.</p> <p>21 Q. And I guess -- on your invoices you break</p> <p>22 it up into expenses and honorarium; is that right?</p> <p>23 A. Correct.</p> <p>24 Q. What do you mean by honorarium?</p> <p>25 A. Other fees other than expenses.</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Why do you call them "honorariums" instead</p> <p>2 of "fees"?</p> <p>3 A. No particular reason.</p> <p>4 Q. I mean, do they go to some organization or</p> <p>5 something other than yourself?</p> <p>6 A. No.</p> <p>7 Q. They're paid to Jason and Jarvis</p> <p>8 Associates LLC; is that right?</p> <p>9 A. Correct.</p> <p>10 Q. And you're an owner of Jason and Jarvis</p> <p>11 Associates LLC?</p> <p>12 A. Correct.</p> <p>13 Q. Who is Jason?</p> <p>14 A. Dr. Janine Jason, my wife.</p> <p>15 Q. And the two of you are the sole owners of</p> <p>16 it?</p> <p>17 A. Correct.</p> <p>18 Q. And the next invoice is from May 21, 2016.</p> <p>19 And that reflects charges related to the Science Day</p> <p>20 meeting in Minneapolis on May 17 through the 18th;</p> <p>21 is that right?</p> <p>22 MR. B. GORDON: I'm just for the record</p> <p>23 going to object to any inquiry concerning Science</p> <p>24 Day. I realize you're not going into the substance</p> <p>25 of it, but I just want to make sure I'm not waiving</p>

Page 14

1 it.

2 BY MR. C. GORDON:

3 Q. Right. I don't intend to get into the
4 substance. But I just --

5 A. Correct.

6 Q. This is the bill related to your
7 appearance at that Science Day; right?

8 A. Correct.

9 Q. And August -- the next one is August 4.
10 And this would be a meeting in Portland, Oregon on
11 July 24 through 25; is that right?

12 A. That's correct.

13 Q. And up to this point have all these
14 meetings been just with lawyers or have there been
15 other non- -- any other non-lawyers involved in the
16 meetings?

17 A. I'm not sure I remember the attendees at
18 all of the different meetings. But there certainly
19 were non-lawyers at some of the meetings, yes.

20 Q. The last invoice in the pile that reflects
21 a meeting in Los Angeles with Dr. Samet and the Bair
22 Hugger team; right; is that right?

23 A. Correct.

24 Q. And we don't have to go through the other
25 invoices just -- well, the August 4, 2016 reflects

Page 15

1 another meeting in Portland but does not identify
2 participants. And the December 2016 looks like it's
3 all review of materials; is that right?

4 A. Correct.

5 Q. And the March 18 one is a meeting in
6 Pensacola, Florida in February; right?

7 A. Corrects.

8 Q. So -- and then the final invoice that we
9 have here in Exhibit 2 is from March 23 and reflects
10 a meeting in LA with Dr. Samet and the Bair Hugger
11 team on March 21, 2017; is that right?

12 A. Correct.

13 Q. And by the Bair Hugger team, is there
14 anybody involved that you consider part of the Bair
15 Hugger who was not a lawyer?

16 A. Again, I don't remember all the attendees
17 but I think other than Dr. Samet's staff, that would
18 probably be correct.

19 Q. Was there anybody else from Dr. Samet's
20 staff that you recall?

21 A. Yes.

22 Q. Do you recall either who that person or
23 people was or were?

24 A. I don't remember the person's name but I
25 think it was an assistant.

Page 16

1 Q. Male or female?

2 A. Female.

3 Q. Do you know if she was a physician?

4 A. I don't remember what her credentials
5 were.

6 Q. Other than this meeting at -- with
7 Dr. Samet and his assistant that's reflected in your
8 invoice -- in your invoices, what other non-lawyers
9 have participated in meetings that you recall? And
10 if you don't remember names, if you can describe
11 what you understood their background or their role
12 to be.

13 A. I don't remember that I remember them all.
14 Or even if -- who was at each of these specific
15 meetings. Certainly one case one of the other
16 experts was at the meeting. Obviously Science Day
17 was the same.

18 Q. Which other expert was at a meeting that
19 you remember?

20 A. One in Atlanta I believe Mr. Koenigsberg
21 [sic] was there.

22 MR. B. GORDON: K-O-E-N-I-G-S-H-O-F-E-R.
23 Koenigshofer.

24 BY MR. C. GORDON:

25 Q. One time?

Page 17

1 A. I believe so.

2 Q. And besides Mr. Koenigshofer and yourself
3 were there any other non-lawyers present at that
4 one?

5 A. As I say, I don't remember specifically
6 all the people who happened to be there. I don't
7 believe there was.

8 Q. Did you have any meetings with
9 Dr. Stonington?

10 A. No. In-person meeting? No.

11 Q. Did you have any phone calls with him?

12 A. I'm trying to remember. I may have had
13 phone calls. Certainly had e-mail exchange.

14 Q. What were you exchanging e-mails with
15 Dr. Stonington on?

16 A. I believe he had a couple of questions.

17 Q. He had questions for you?

18 A. Correct.

19 Q. Did you have any questions for him?

20 A. No.

21 Q. Do you remember what those questions were
22 generally?

23 A. Not really, no.

24 Q. Were you able to answer them?

25 A. I sent a response back. You'd have to ask

Page 18

1 him if it answered the question adequately or not.

2 Q. Did you have any communication with
3 Mr. Buck?

4 A. I don't believe.

5 Q. How about Dr. Elghobashi? Did you have
6 any communication with him?

7 A. No.

8 Q. How about Yadin David? Did you have any
9 communications with him?

10 MR. B. GORDON: Yadin.

11 MR. ASSAAD: David.

12 MR. B. GORDON: Yadin/David.

13 BY MR. C. GORDON:

14 Q. I guess in America he goes by David.

15 A. No.

16 Q. Dr. David.

17 Okay. Anyone else that you can remember
18 that you've had meetings with in connection with the
19 Bair Hugger case who was not a lawyer?

20 A. Not that I recall.

21 Q. The invoices that we've marked as
22 Exhibit 2, those reflect all your work on the Bair
23 Hugger litigation through March 23, 2017; is that
24 right?

25 A. Correct.

Page 19

1 Q. And I assume that there has been or will
2 be an invoice subsequent to the March 23, 2016 that
3 would reflect the time you spent in preparing your
4 expert report that was served on March 31, 2017?

5 A. Correct.

6 Q. So would it be correct to conclude from
7 these invoices that you did all the writing of your
8 report between March 23 and March 31, 2017; is that
9 right?

10 A. I think probably some before that as well.

11 Q. And help me out here. Any -- you know --
12 there was one invoice where you reviewed some should
13 materials back in December of 2016 but I -- but
14 that's the only one I think that appears to be
15 review of materials as opposed to meetings; am I
16 right?

17 A. There -- I think there -- you could assume
18 correctly that there would have been review of
19 materials all along the way.

20 Q. Oh, okay. It's just not separately called
21 out?

22 A. Correct.

23 Q. Now on that December 28, 2016, so long as
24 we're on it, one of the things -- one of the items
25 of your activities, it says, "Protocol Bair Hugger

Page 20

1 study development and revisions," 13 hours there.
2 What's that a reference to?

3 A. Developing a protocol for a study.

4 Q. What kind of study?

5 A. Assessing the Bair Hugger.

6 MR. B. GORDON: I'm going to object to the
7 extent this calls for any of the substance of any
8 consulting he did with us on what we believe is work
9 product privilege information. Obviously he can
10 disclose what he has disclosed. But in terms of the
11 substance of any proposed study that didn't happen,
12 we object to that as being protected by the work
13 product privilege.

14 BY MR. C. GORDON:

15 Q. Have you conducted any studies in
16 connection with the Bair Hugger?

17 A. No.

18 Q. Are you aware of anyone else other than
19 Mr. Buck, one of the other plaintiff's experts who
20 has done any study of the Bair Hugger as part of
21 this litigation?

22 MR. B. GORDON: Yeah, if you came to know
23 anything like that through counsel, then I'm
24 instructing you not to answer. It would be
25 privileged.

Page 21

1 THE WITNESS: I guess it depends on how
2 you word "study." You know, is review of material
3 study? Or you mean actually conduct in vitro study
4 of some sort?

5 BY MR. C. GORDON:

6 Q. Well, in vitro or in vivo, or I guess I
7 want to limit it as an epidemiologist you would --
8 you could do a study reviewing, say, medical
9 records; right?

10 MR. B. GORDON: Hang on just a second,
11 Doctor.

12 I'm not sure what the question is, Corey.

13 BY MR. C. GORDON:

14 Q. Well, I just -- that was more of a
15 response. I don't want to be very narrow. I'm just
16 wondering if you are aware of any studies -- whether
17 they're epidemiological, in vivo, in vitro, lab
18 experiments, anything of that nature -- that were
19 conducted with respect to the Bair Hugger of which
20 you were apprised?

21 MR. B. GORDON: Before you answer, I'm
22 going to object to the extent that anything you came
23 to know -- if anything -- through counsel is
24 protected by the work product privilege and instruct
25 you not to answer. If you know of such studies

1 outside of any discussions with us, then you're free
2 to answer.

3 THE WITNESS: Yeah, I would say excluding
4 review of literature, actually conducting hands-on a
5 study? No.

6 BY MR. C. GORDON:

7 Q. Okay. You haven't done any studies;
8 that's what you're saying?

9 A. Or aware of other experts.

10 Q. Or aware of any. Okay.

11 And now Mr. Buck --

12 A. With the exception of Dr. Elghobashi
13 obviously.

14 Q. Fair enough. I left that out.
15 Unintentionally.

16 So you're aware that Mr. Buck did a study
17 where he measured particles in an experimental
18 setup; right?

19 A. Correct.

20 Q. And you're aware that Dr. Elghobashi
21 commissioned a -- or directed a preparation of a
22 computation fluid dynamics model? Are you aware of
23 that?

24 A. Correct.

25 Q. And the protocol that you spent 13 hours

1 developing and revising, did that have anything to
2 do with either Mr. Buck's experiments or
3 Dr. Elghobashi's CFD model?

4 A. No.

5 Q. Mr. Buck measured particles in his
6 report -- in his experiment that was reflected in
7 his expert report. Were you familiar with that?

8 A. Correct.

9 Q. You read his report?

10 A. I did.

11 Q. Were you present when he did his
12 experiments?

13 A. No.

14 Q. Do you know if he measured -- attempted to
15 measure bacteria?

16 A. I'd have to go back and look at it. I
17 don't believe he did.

18 Q. Would you agree that it would make -- from
19 a scientific standpoint, that measuring bacteria is
20 more relevant to issues relating to infection than
21 measuring particles?

22 MR. B. GORDON: Object to the form.
23 Assumes facts not in evidence.

24 THE WITNESS: Yeah, I guess I wouldn't use
25 the word "more relevant." I think it adds other

1 information.

2 BY MR. C. GORDON:

3 Q. We'll get to that further.

4 So in coming to your opinions, did you
5 rely on any experimental evidence, including
6 anything that might have come out of your Bair
7 Hugger study protocol that you developed over 13
8 hours that in any way informed your opinions?

9 A. I guess I'd ask you to reword that. I'm
10 not sure --

11 Q. Okay.

12 A. -- what you're asking.

13 Q. You considered the Buck study. You
14 considered the Elghobashi CFD; right?

15 A. Right.

16 Q. You developed a Bair Hugger study protocol
17 that is apparently distinct from either Mr. Buck's
18 or Dr. Elghobashi's works -- work; right?

19 A. Correct.

20 Q. Okay. And did anything conducted pursuant
21 to or related to that Bair Hugger study protocol in
22 any way inform your expert opinion?

23 MR. B. GORDON: Object to the form.
24 Vague.

25 THE WITNESS: Well, obviously in

1 developing the protocol, that included extensive
2 review of the medical literature as well. So it
3 kind of goes with looking at all of the scientific
4 data about the Bair Hugger.

5 BY MR. C. GORDON:

6 Q. Right. What I'm -- but what I'm asking
7 about is if any study came out of the protocol that
8 you developed and you were apprised of any results,
9 did any of that inform -- if there was such a study,
10 any kind of study conducted and if the results of it
11 were shared with you, did that in any way inform
12 your expert opinion?

13 A. No.

14 Q. Do you have an estimate as to how much
15 time you would have expended in preparing your
16 report that's not reflected in these invoices?

17 A. Not offhand.

18 Q. Just kind of eyeballing these invoices in
19 Exhibit 2, it looks like they total about \$90,000.
20 Does that sound about right?

21 A. Probably in the ballpark, yeah.

22 Q. And subsequent to March 23, 2017, do you
23 have any estimate as to how much additional time
24 you've billed or -- either in time or in dollars for
25 fees?

1 A. No.
2 Q. Do you have any estimate as to how much
3 time you took in preparing your report?
4 A. Not offhand.
5 (Exhibit 3 marked.)
6 BY MR. C. GORDON:
7 Q. This morning your lawyer Mr. Gordon --
8 Mr. Ben Gordon -- handed me a document I've marked
9 as Exhibit 3 entitled "Jarvis Additional Materials
10 Reviewed." Do you see that?
11 A. Yes, sir.
12 Q. Is that -- is it something you prepared?
13 A. Yes.
14 Q. And just looking at the list of expert
15 reports that start on the second page, it would
16 appear that this includes at least some materials
17 that did not exist at the time you did your initial
18 report; is that right?
19 A. That would be correct.
20 Q. So when it refers to "Additional Materials
21 Reviewed," when were these additional materials
22 reviewed by you?
23 A. Some of these probably -- some of these
24 definitely were reviewed before I drafted my report;
25 they just weren't referenced in that report. And

1 you -- you were requesting all information in your
2 subpoena that I looked at. So some of it is
3 reflective of that and others are articles that I've
4 found and/or read since I wrote that report.
5 Q. Okay. Well, obviously something that you
6 hadn't reviewed prior to your report you couldn't
7 have referenced. But if something is on Exhibit 3
8 that you reviewed prior to your report but didn't
9 include in your references, what -- what should we
10 take away from that, that you reviewed it but
11 considered it not relevant to your report or --
12 MR. B. GORDON: Object to the form.
13 BY MR. C. GORDON:
14 Q. Tell me how -- tell me what the
15 distinction you made between --
16 A. Well, there's --
17 Q. -- what you listed as references and what
18 you listed as materials reviewed.
19 A. I would say the references in the report
20 are peer-reviewed articles primarily that
21 substantiate or describe or support various points
22 that I'm making in the report. So if I read
23 something that might have scientific interest and be
24 relevant but I didn't refer to it in my report, then
25 I wouldn't reference it.

1 Q. I want to ask you something about your
2 report in -- that's Exhibit 1. On page 25 in the
3 summary section you say, "In summary, having applied
4 the methodological 'gold standard' approach which I
5 used in my work for the CDC, I have come to the
6 conclusion that" and then you go on to enumerate the
7 details of your opinion; correct?
8 A. Correct.
9 Q. What is the methodological gold standard
10 approach that you used in your work for the CDC that
11 you applied to coming up with your expert report?
12 A. Well, some of that is described on page 3
13 of that report and involves investigation of
14 outbreaks, and other parts are described in other
15 parts of the report that refer to extensive critical
16 review of the literature that is involved in
17 development of guideline recommendations when I was
18 at CDC.
19 Q. Okay. I'm a little confused here. On
20 Exhibit -- excuse me. On page 3 of Exhibit 1, when
21 you're talking about outbreak investigations that
22 you did in the CDC, did you do anything similar to
23 any outbreak investigations you did at the CDC in
24 connection with the Bair Hugger litigation?
25 A. Well, some of it. Some of it talking

1 about a systematic review to do things.
2 Q. A systematic review of literature?
3 A. Correct.
4 Q. I understand that and I want to talk about
5 it. I just want to -- again, I'm -- I just want to
6 make sure you -- you didn't do any independent
7 outbreak investigation --
8 MR. B. GORDON: Object to the form --
9 BY MR. C. GORDON:
10 Q. -- did you?
11 MR. B. GORDON: -- and counsel's
12 characterization.
13 THE WITNESS: If you're talking about did
14 I go on-site to a variety of hospitals, review
15 medical records of parties that either had an
16 exposure or did not have an exposure to the Bair
17 Hugger, that would be correct.
18 BY MR. C. GORDON:
19 Q. I'm just trying to understand what -- I
20 mean, when you were at the CDC, you did outbreak
21 investigations; right? You talk about that on page
22 3.
23 A. Correct.
24 Q. And that -- and I think you were just
25 saying now that when you refer to the CDC

1 methodological gold standard, that includes --
2 included outbreak investigations.

3 A. Correct. And that outbreak investigation
4 includes an epidemiologic component and often a
5 laboratory component. And in my review of the
6 literature on the Bair Hugger, I included
7 epidemiologic studies that included both laboratory
8 as well as clinical studies.

9 Q. Your report, however, is based, I think,
10 with the exception of reliance on Dr. Elghobashi's
11 CFD. Correct me if I'm wrong. Otherwise it's --
12 it's completely based on your -- your systematic
13 review of the medical literature --

14 MR. B. GORDON: Objection to form --
15 BY MR. C. GORDON:

16 Q. -- is that right?

17 MR. B. GORDON: -- asked and answered and
18 described in his report. Mischaracterizes the
19 evidence.

20 BY MR. C. GORDON:

21 Q. Yeah, I don't want to mischaracterize.
22 I'm trying to understand what you're saying.

23 A. I would say that's correct, with the
24 addition of it also includes my clinical training
25 and epidemiologic experience. So it's a combination

1 of all of those.

2 Q. Right. But in terms of the methodological
3 gold standard that you used at the CDC, did you do
4 anything other than a systematic review of the
5 literature?

6 A. In this case it was primarily a systematic
7 review of the literature.

8 Q. You say "primarily," and that's why I'm --
9 I don't mean to pick nits here but did you do
10 anything secondarily?

11 A. Well, for instance Dr. Elghobashi's study
12 is not a peer-reviewed study in the literature --

13 Q. Okay.

14 A. -- so I looked at that.

15 Q. Anything else?

16 A. Mr. Buck's study is again not a
17 peer-reviewed study. And there are one or two
18 abstracts that I looked at as well. But it's
19 primarily work that others have done primarily being
20 peer-reviewed literature.

21 Q. Okay. And you reference Dr. Elghobashi's
22 CFD in your report. Had you read Mr. Buck's report
23 or at least knew of the results of his -- his
24 experiments before you wrote your report?

25 A. I don't remember when I first saw that.

1 Q. Okay. And I'm -- I probably wasn't clear.
2 Let me try to be clear here. I'm trying to focus in
3 and learn everything you did and everything you
4 considered in arriving at your opinion on or before
5 March 31, 2017. Okay?

6 A. Okay.

7 Q. Anything you've done subsequently we'll
8 talk about that separately, but this questioning I'm
9 trying to focus on what -- what were the things you
10 reviewed and considered that informed your expert
11 opinion as of March 31, 2017. Okay?

12 A. Okay.

13 Q. Let's go back to your "Additional
14 Materials Reviewed," Exhibit 3. And you said you
15 think some of these you had -- or you -- I don't
16 want to characterize that. Some of these materials
17 reviewed that do not appear on your list of
18 references were nonetheless things you would have
19 read and considered prior to March 31, 2017; is that
20 correct?

21 A. Correct.

22 Q. Are you able to go through and identify
23 those that you would have read prior to March 31,
24 2017?

25 A. Some I would know; some I don't know. I'd

1 be guessing.

2 Q. Okay. Well, why don't you look at the
3 list on Exhibit 3 and let's -- and I'm -- at this
4 point I'm just focusing on articles. We'll get to
5 depositions and expert reports later. But of the
6 articles listed on Exhibit 3, can you identify any
7 of those that, yes, you know for sure you read that
8 prior to March 31, 2017?

9 A. As I say, some I could say definitively.
10 Others would be a guess.

11 Q. Okay. Tell me the ones you know to be
12 definitively.

13 A. Tuimia; Leaper; Lidwell, both.

14 Q. I think you did -- you've cited a couple
15 of Lidwells in your references. Are these
16 different?

17 A. They're different. I believe.

18 Q. Okay. Fair enough.

19 A. Kirksey.

20 (Reporter asks for repetition.)

21 Q. I'm sorry. What's --

22 A. Kirksey, K-I-R-K-S-E-Y.

23 Noble, Petty, Memarzadeh, Sharp. I
24 believe Kuhme.

25 Q. Which one?

Page 34

1 A. Kuhme.
 2 Q. K-U-H-M-E?
 3 A. Mm-hmm.
 4 Sikka, Fletcher, Tande, Cram. I'm not
 5 sure about the anesthesiology paper. Brown.
 6 Q. You're talking about Brown 2012; right?
 7 A. Right.
 8 The FDA website for heater coolers was
 9 both before and after. It's constantly changing.
 10 The CDC update. The FDA safety
 11 communication.
 12 The Parvizi study.
 13 (Reporter asks for repetition.)
 14 Parvizi, P-A-R-V-I-Z-I.
 15 And Augustine 2014, I believe; not 2017.
 16 Q. Okay.
 17 A. The others I'd be guessing.
 18 Q. Okay. And you said definitively, though,
 19 that you had not reviewed Augustine 2017 prior to
 20 your two reports; is that right?
 21 A. I'm not sure on that. I don't remember
 22 the date. I think it was after, but I'm not sure.
 23 Q. All right. We'll talk about that in a
 24 little bit. But of the ones that you can't
 25 definitively remember, are there any that you can

Page 35

1 look at and say yeah, you know, I definitely had not
 2 seen that before March 31?
 3 A. By name, no. I'd have to look at the
 4 paper and look at the title; it might jog my memory.
 5 Q. Are there any subject matters reflected in
 6 any of these articles that you know that yeah, I
 7 hadn't looked at that prior to March 31, but I did
 8 look at -- look at that afterwards?
 9 A. Oh, I think globally in terms of subject
 10 matters they probably all are in this same realm.
 11 Q. Okay. How did you select the materials to
 12 review prior to rendering your opinion?
 13 A. Combination of materials sent to me by
 14 counsel and many, many, many reviews of the
 15 literature both Google and PubMed.
 16 Q. Do you recall what your search parameters
 17 or criteria were for your Google or PubMed searches?
 18 A. Probably almost every combination you can
 19 think of. Forced air warmers, infections, surgical
 20 site infections -- prosthetic --
 21 (Reporter asks for repetition.)
 22 Forced air warmers, surgical site
 23 infections, prosthetic joint infections, Bair
 24 Hugger, normothermia, hypothermia. Crossed with --
 25 surgical site infections with various organisms and

Page 36

1 normothermia, hypothermia, Bair Hugger, forced air
 2 warmers.
 3 Also looking at the various papers and
 4 looking at the references of those papers and going
 5 and reading those.
 6 So as broad as I could possibly be of
 7 anything that was out there.
 8 Q. Again, going back to your invoices on
 9 Exhibit 2. The only specific reference I see -- and
 10 I could be wrong, so please don't rely on me -- but
 11 the only reference I'm seeing specifically to review
 12 of any literature review was in the December 28,
 13 2016 invoice. And that's really my question. Did I
 14 miss any? Are there any other places where you
 15 included in your invoice time for reviewing
 16 literature?
 17 A. Well, for instance, on August 4
 18 pre-meeting preparation --
 19 Q. Okay.
 20 A. -- may well include that.
 21 Q. Well, and -- let's talk about that for a
 22 second because pre-meeting preparation appears on
 23 several of these. So I -- if -- let's -- let's
 24 address that.
 25 Pre-meeting preparation would -- could

Page 37

1 have included some of the literature review and the
 2 search -- searches that you did on Google and
 3 PubMed; is that right?
 4 A. That's right.
 5 MR. B. GORDON: Asked and answered.
 6 BY MR. C. GORDON:
 7 Q. So on April 13, 2016 there were -- you
 8 billed for two hours of pre-meeting preparation;
 9 right?
 10 A. Correct.
 11 Q. And on May 11, 2016 you billed for five
 12 hours of pre-meeting preparation; is that correct?
 13 A. Correct.
 14 Q. May 21, 2016, another five hours of
 15 pre-meeting preparation; is that right?
 16 A. Correct.
 17 Q. And August 4, 2016. That would be three
 18 hours of pre-meeting preparation; is that right?
 19 A. Correct.
 20 Q. December 28. That would be the one where
 21 you billed specifically two hours for literature
 22 review; right?
 23 A. What date was that, please?
 24 Q. December 28, 2016.
 25 A. Correct. But protocol development and

10 (Pages 34 to 37)

1 revision does include that as well.

2 Q. Okay. So -- do you have an estimate as to
3 what portion of the 13 hours you billed for protocol
4 development and revision was actually spent in
5 reviewing -- searching and reviewing literature on
6 Google or PubMed?

7 A. Not offhand, no.

8 Q. Okay. And March 18, I don't see any
9 pre-meeting prep; am I missing it?

10 A. No. There's none there.

11 Q. And March 23, again no -- no pre-meeting
12 prep that I see; is that right?

13 A. Correct.

14 Q. Okay. So in terms of pre-meeting prep
15 that -- if my math is correct, that would be a total
16 of 15 hours; right?

17 A. That could be correct.

18 Q. And a total of -- well, 13 hours for the
19 protocol development that involved -- may have
20 involved some review of literature; right?

21 A. It did, yes.

22 Q. And two hours specifically for literature
23 review; right?

24 A. Correct.

25 Q. So that's -- again, if my math is correct,

1 that's a total of 30 hours. Does that sound about
2 right for the amount of time that you would have
3 done research using all those search parameters that
4 you just described on Google and PubMed?

5 A. You mean just doing the searches
6 themselves or reading the materials that resulted
7 from those searches?

8 Q. More of the latter. Reviewing -- well,
9 both. Doing the searches and reading whatever it is
10 you -- the searches generated.

11 A. Well, I would say that's accurate. Maybe
12 even an underestimate, yeah.

13 Q. An underestimate?

14 A. It could be, yeah.

15 Q. Do you think that the \$90,000 or so that
16 you billed through March 23, 2017 is -- you
17 underbilled? You didn't cover all your time?

18 MR. B. GORDON: Objection to form. Lack
19 of foundation. Argumentative.

20 THE WITNESS: No. I think it's accurate.
21 BY MR. C. GORDON:

22 Q. Okay. Again, all I have are your invoices
23 from March 23, 2017. So I'm just trying to
24 understand.

25 Other than those -- the 30 total hours in

1 those three different categories, is there anything
2 else that would have covered the time -- any amount
3 of time that you spent in doing the Google and
4 PubMed research and review of literature?

5 MR. B. GORDON: Objection to form. Vague.

6 THE WITNESS: No, I think that covers it.

7 BY MR. C. GORDON:

8 Q. Between March 23 and when you finalized
9 your report on or about March 31, 2017, do you have
10 an estimate as -- well, first of all, did you do any
11 additional PubMed, Google search -- searches?

12 A. Yes. Probably did, yeah.

13 Q. Any estimate as to how much additional
14 time you did?

15 A. Not offhand.

16 Q. So of the references you cited in
17 Exhibit 1, what -- what percentage of those came as
18 a result of your Google and PubMed searches versus
19 some other means of gathering these?

20 MR. B. GORDON: Objection. Nitpicking
21 again.

22 THE WITNESS: Yeah, I don't know that I
23 could tell you exactly.

24 BY MR. C. GORDON:

25 Q. Some of the --

1 A. I would say the majority are from my
2 searches.

3 Q. Okay. And would it be correct to say
4 the -- most of the remainder would have come in
5 materials provided to you by counsel?

6 A. Well, that -- that makes it some, yes.

7 Q. I don't want to presume that there was any
8 other source.

9 So on Exhibit 3, the "Additional Materials
10 Reviewed," just again those ones that you identified
11 definitively as ones that you would have reviewed
12 prior to issuing your report, can you -- do you know
13 which ones of those came as a result of your
14 independent search versus what you were provided by
15 counsel?

16 A. Not offhand. But I'd say the majority are
17 my searches.

18 MR. B. GORDON: I'll stipulate we provided
19 him with depositions and the --

20 MR. C. GORDON: I'm just --

21 MR. B. GORDON: -- expert reports.

22 MR. C. GORDON: -- talking about the
23 articles.

24 THE WITNESS: Yeah, I'm just talking about
25 the articles too. I'd say the majority are from my

1 searches.

2 BY MR. C. GORDON:

3 Q. And how did -- what was your yardstick for
4 determining whether the materials that you reviewed
5 listed in Exhibit 3 but didn't include in your
6 references, what was the yardstick by which you
7 decided no, I'm not going to include that as a
8 reference?

9 MR. B. GORDON: Objection to form. Vague.

10 THE WITNESS: Well, I'd say what's usually
11 done is if you are writing a journal article or
12 you're writing a -- at least when I'm writing a
13 report if I'm substantiating a point or I'm
14 particularly quoting or using materials from a
15 publication, I would give that reference.

16 Many of these talk about -- many of these
17 papers that I didn't reference are talking about
18 organisms on the skin, dispersion intensive -- in an
19 operating room, surgical site surveillance,
20 et cetera, et cetera. And if I didn't quote from
21 them in the report, I didn't reference them.

22 BY MR. C. GORDON:

23 Q. Because they didn't substantiate a point
24 you were making; is that right?

25 A. Well, not necessarily. In many cases they

1 do substantiate the points that I'm making but
2 they're not what I'm specifically quoting. I guess
3 the problem is I could put in 250 references or a
4 thousand references. But what value is that? If
5 I'm referring to Avidan study and I'm quoting
6 something from Avidan study, do I then put in 10
7 other studies that say the same thing? No.

8 Q. Is it your testimony that all the
9 materials that you reviewed prior to March 31, 2017
10 but didn't include in your references are -- in no
11 way question or contradict any of the points you've
12 made?

13 A. I don't know that I would judge them
14 specifically that way. They may have just been
15 studies that I felt were very small studies or I had
16 already made the point with another -- other
17 reference.

18 Q. In describing the CDC methodological gold
19 standard, you use the phrase "systematic review";
20 right?

21 A. Correct.

22 Q. Explain what you mean by "systematic
23 review" in that context.

24 A. Well, an example of it would be in
25 Dr. Wenzel's report where he seems to take all the

1 things that -- all of -- well, not all but many of
2 the references he used is -- are to substantiate his
3 point of view and ignores the huge body of the
4 literature that doesn't agree with him.

5 Q. So what is a systematic review?

6 A. To me a systematic review is you try to
7 look at every article that you can find. And I try
8 to do that with my Google and PubMed searches that
9 address the specific questions that we're trying to
10 answer and not go in and pick two that I like that
11 support my point of view and ignore 10 that refute
12 it.

13 Q. So a systematic review would be not
14 cherry-picking only those things that support a
15 point you're trying to make; right?

16 A. Right.

17 MR. B. GORDON: Object to the
18 characterization.

19 THE WITNESS: Unbiased review of the
20 existing peer review literature.

21 BY MR. C. GORDON:

22 Q. So that methodological gold standard that
23 you applied in coming to your opinion, that included
24 trying to review all the relevant literature and not
25 picking and choosing things based on whether they

1 supported or didn't support whatever opinions you
2 were trying to make; is that right?

3 A. Tried to do that.

4 Q. And again going back to that
5 methodological gold standard that you talked about
6 with the CDC, the way the CDC came up with
7 guidelines or did investigations was not to achieve
8 a preconceived conclusion, but to see where the
9 evidence led; right?

10 A. That's what we try to do.

11 Q. And that's what you tried to do in your
12 report; right?

13 A. Correct.

14 Q. You didn't start out with a "I'm going to
15 see what I can find to support this." You entered
16 it with an open mind; right?

17 A. I tried to.

18 Q. And if you found something that called
19 into question any of the conclusions that you were
20 formulating at that point, you considered that and
21 determined whether maybe you should step back and
22 maybe think back whatever conclusion you were
23 formulating; right?

24 A. Correct.

25 Q. Now, you've indicated that some of these

1 articles listed on Exhibit 3 you may have reviewed
2 after your report; is that right?

3 A. Correct.

4 Q. Are there any articles that you reviewed
5 after you issued your opinion that in any way made
6 you think well, gee, if I had been aware of this
7 before I issued my opinion, I would have maybe
8 changed a conclusion or at least noted some
9 disagreement?

10 A. I don't think so.

11 Q. One of the conclusions -- well, strike
12 that.

13 Beginning on the bottom of page 14 of your
14 report, Exhibit 1, you talk about airborne
15 particulates and CFUs; is that right?

16 A. Yes.

17 Q. And you quote -- or you -- you cite to
18 five different papers there; right?

19 A. Correct.

20 Q. And you say, "Cumulatively these studies
21 show that airborne particle counts and microbial
22 CFUs can be elevated near or at the operative
23 incision site and that activities that increase the
24 particle counts, microbial CFUs increase the risk of
25 SSL." Correct?

1 A. Correct.

2 Q. Now, one of the things on your list of
3 additional materials, Exhibit 3, is something
4 identified as Cristina Exhibit 12? All right.
5 Excuse me. 2012. Is that right?

6 A. Correct.

7 (Exhibit 4 marked.)

8 BY MR. C. GORDON:

9 Q. And I'm going to show you what I've marked
10 as Exhibit 4 and ask you if this Exhibit 4 appears
11 to be the Cristina 2012 article that you included in
12 your "Additional Materials Reviewed," Exhibit 3.

13 MR. B. GORDON: I thought you didn't like
14 Italy, Corey?

15 MR. C. GORDON: Who said that? I love
16 Italy.

17 MR. B. GORDON: The memo you filed
18 yesterday or the day before.

19 I'm just messing with you.

20 THE WITNESS: Correct.

21 BY MR. C. GORDON:

22 Q. So the -- and I'll certainly take time to
23 look at it if you need to, but can you tell me if
24 this is an article that you would have reviewed
25 prior to or after you rendered your opinion?

1 A. I don't remember.

2 Q. Do you need to review to know basically
3 what it says?

4 A. I think I remember some of it, yes.

5 Q. And would you agree that basically this
6 was a study in orthopedic operating theaters and the
7 authors concluded that particle counts did not
8 correlate with bacterial colony-forming units?

9 MR. B. GORDON: Object to counsel's
10 characterization. Document speaks for itself.

11 THE WITNESS: Repeat your question,
12 please?

13 MR. C. GORDON: Could you read it back.

14 (Record read as follows:

15 "Q. And would you agree that basically
16 this was a study in orthopedic operating
17 theaters and the authors concluded that
18 particle counts did not correlate with
19 bacterial colony-forming units?")

20 MR. B. GORDON: Same objection.

21 THE WITNESS: Well, I think it was more
22 limited than that in they do point out that neither
23 fraction of their particulates -- and they only
24 looked at two that is greater or equal to
25 0.5 microns or greater or equal to 5 microns -- that

1 that was not correlated with microbial load in the
2 types of procedures they specifically examined.

3 As I recall it, procedures were short. I
4 can't remember whether they had laminar flow or not.
5 And they pointed out that they had a number of
6 limitations in the study and it did not rule out the
7 possibility of a correlation if they looked at other
8 particle sizes.

9 BY MR. C. GORDON:

10 Q. So the fact they pointed out limitations,
11 that was one reason you decided not to include it in
12 what you considered or what you referenced in your
13 report?

14 MR. B. GORDON: Object to form.

15 THE WITNESS: Well, I think it -- there
16 were a number of other things that I think were odd
17 about it as well. I can't remember if this is the
18 one that found that -- let me look here.

19 As I say, I don't remember if I read this
20 before or after. Another possibility also is,
21 again, I used my experience and background with the
22 CDC. And I have done a fair amount of work in
23 Italy. And their operating rooms don't tend to be
24 to the same standard, I would say, as an operating
25 room in the United States.

Page 50

1 But I think my primary concern was that
2 they only looked at two specific rather than a
3 broader range of particles. But they still found,
4 you know, 35 colony-forming units per meter squared
5 as a bacterial load in the operating room which is
6 consistent with, again, finding airborne particles
7 in the operating room. They just didn't find a
8 correlation, but they were looking at too specific
9 particle counts, not a wide range.

10 BY MR. C. GORDON:

11 Q. So on that basis you think that this
12 would -- systematic review using the CDC gold
13 standard methodology, this would not be something
14 that would properly be considered in, say, coming up
15 with a CDC guideline; is that right?

16 MR. B. GORDON: Object to the form.

17 THE WITNESS: Well, to be perfectly honest
18 with you, in terms of the CDC guideline it wouldn't.
19 Because right now the CDC guideline doesn't look at
20 anything that's not a randomized control trial. I
21 don't agree with it but that's what they do. So by
22 definition CDC would not look at this at all.

23 (Reporter interruption.)

24 So from CDC's point of view, in terms of
25 their -- for instance a surgical site guideline that

Page 51

1 they have just recently updated, in that document
2 they did not look at any study that was not a
3 randomized control trial.

4 MR. C. GORDON: That's maybe an important
5 distinction that we should talk about. Let me start
6 off by marking Exhibit 5.

7 (Exhibit 5 marked.)

8 BY MR. C. GORDON:

9 Q. Could you tell me what that is, please.

10 A. This is a Centers for Disease Control and
11 Prevention guideline for the prevention of surgical
12 site infections 1999.

13 Q. And you were part of the CDC at that time;
14 right?

15 A. That is correct.

16 Q. And you were part of a group of people who
17 actually pulled together and prepared these
18 guidelines; correct --

19 A. I --

20 Q. -- for this guideline?

21 A. I supervised this guideline.

22 Q. And so when you talk about the CDC
23 methodological gold standard that you applied in
24 coming up with your expert opinion in this case,
25 would that be the same methodology that was employed

Page 52

1 in coming up with the 1999 Exhibit 5?

2 A. To a large extent, yes.

3 Q. Are there any methodological differences?

4 A. Well, obviously here there's a -- what's
5 called the Hospital Infection Control Practices
6 Advisory Committee which is a federal advisory
7 committee. So CDC -- a number of different groups
8 at CDC have advisory committees. This was one for
9 the hospital infections program at the time.

10 And when I look at review of the
11 literature, I look at it personally and make a
12 decision one way or the other. Whereas, in this
13 case this group of people who were all supervised by
14 me as part of my group did the literature search.
15 But then this document after it was drafted was
16 reviewed by the advisory committee. And they had
17 some comments and suggestions on revisions. So that
18 would be different than what I do specifically.

19 Q. I want to be a little bit more narrow in
20 my question. In terms of deciding what literature
21 to review and then what literature to reference in
22 connection with the 1999 guideline, was that
23 methodology any different than what you personally
24 used in searching for, reviewing, and deciding what
25 literature to reference in your opinion?

Page 53

1 A. I'd say generally they would be the same.
2 But if you get the specifics -- you know, this is
3 obviously a very broad guideline. It tries to cover
4 all components of surgical site infection
5 prevention. It in fact is so broad that the recent
6 CDC guideline revision did not undertake to do this
7 broad a view but, rather, focused on -- I think it's
8 either three or four specific surgical procedures.
9 So we went very broad.

10 And I think one difference between what
11 was done here and what I did is I tried to go very
12 deep on a very narrow area: Normothermia,
13 hypothermia, and the risk of infection. And
14 basically methodologies to maintain normothermia and
15 their impact.

16 So I'm going systematically very deep on a
17 relatively narrow aspect. Whereas, this is trying
18 to be comprehensive. But obviously if you're
19 looking at such a broad range of different
20 components, you may not go quite as deep.

21 Q. Again, my question may have been too broad
22 and I -- see if I can clarify it.

23 A few moments ago you said that -- and the
24 record is what it is; I'm not trying to put words in
25 your mouth -- but that the CDC now will only look at

1 randomized control trials; right?

2 A. That's correct.

3 Q. Okay.

4 A. Certainly now. That was not this
5 (indicating).

6 Q. And that's my point. Certainly in
7 Exhibit 5 in the development of the -- this
8 guideline, you and your colleagues looked at a lot
9 of different medical literature beyond randomized
10 control trials; right?

11 A. Contract.

12 Q. And all their -- their 497 references in
13 Exhibit 5; right?

14 A. That's correct.

15 Q. And certainly those include some medical
16 literature that was not based on randomized control
17 trials; right?

18 A. Correct.

19 Q. And so the systematic review that you and
20 your colleagues did for the 1999 surgical site
21 infection guidelines, you're saying that's a
22 different systematic review methodological gold
23 standard than the CDC currently uses; is that right?

24 MR. B. GORDON: Object to form.

25 THE WITNESS: Well, the CDC approach to

1 guideline development has changed in a large number
2 of ways over the years.

3 At the time this guideline was written,
4 CDC staff did all of the review and all the drafting
5 of the guideline and then the advisory committee
6 then reviewed and gave their comments and
7 suggestions, potential additions, et cetera. That
8 has changed dramatically.

9 And now CDC basically farms out the
10 guideline development. This guideline took us two
11 years. It's very resource-intensive,
12 personnel-intensive. And management in the division
13 decided that that was overburdensome.

14 And so now the guideline development
15 process is very different with outside -- basically
16 contractors doing it. And then it's brought back
17 into the advisory committee and the division and
18 reviewed and revised.

19 So the whole process of how it's done and
20 the literature upon which the guideline is based has
21 kind of evolved and changed over the years.

22 BY MR. C. GORDON:

23 Q. I'd like to focus on the literature aspect
24 of it, not the subcontracting and how -- how things
25 developed.

1 Has the CDC changed its requirements for
2 what literature can be considered in developing
3 guidelines from the time you developed the 1999
4 guideline?

5 A. I would say that the literature that is
6 used in the development of the guideline varies by
7 guideline. For instance, the hand hygiene guideline
8 was developed in 2002. And someday -- since it's --
9 what? -- 15 years old now, that guideline will be
10 revised. If they limit themselves to randomized
11 control trials, which they did with the surgical
12 site update, there will be no guideline. Because
13 there's not a single randomized control trial. So
14 the inclusion criteria for the guideline changes by
15 guideline.

16 Q. Where does one -- where would one find the
17 inclusion criteria for the CDC's surgical site
18 infection guidelines?

19 A. I would think it would be in -- I don't
20 know that they ever actually enumerate specifically
21 on the inclusion criteria. I think now the CDC
22 guidelines tend to have huge appendices that give
23 kind of an algorithm for how they went about their
24 review and what article -- well, at least in terms
25 of how many articles are included, how many

1 excluded, that type of thing.

2 MR. C. GORDON: Well, let's see if you can
3 help me out here. I'm going to show you Exhibit 6.
4 (Exhibit 6 marked.)

5 BY MR. C. GORDON:

6 Q. And can you identify what Exhibit 6 is?

7 A. I believe this is the updated guideline
8 that I mentioned that's much more limited, much more
9 focused.

10 Q. And on the -- this would be the 2017
11 surgical site -- surgical site infection guideline
12 update; right?

13 A. Correct.

14 Q. Okay. And there's -- under "Evidence
15 Review," it refers to "A modified Grading of
16 Recommendations, Assessment, Development, and
17 Evaluation (GRADE) approach." Do you see that?

18 A. Where are you reading that?

19 Q. Under the -- very first page, under
20 "Evidence Review."

21 A. Correct.

22 Q. Do you have any idea what the -- what that
23 "Grading of Recommendations, Assessment,
24 Development, and Evaluation" concept is?

25 A. Yes.

1 Q. What is it?

2 A. This was proposed probably 15 years ago
3 perhaps. And it's a grading of published
4 peer-reviewed study articles with the highest grade
5 being given to randomized control trial, systematic
6 reviews and metaanalyses. And -- I can't go into all
7 of the details of it, but it talks about the design
8 of the study, potential biases in the study, that
9 type of thing.

10 And -- so this is where I mention that
11 they have become much more focused on randomized
12 control trials and looking at before/after studies,
13 case control, cohort, other epidemiologic studies.

14 (Reporter asks for repetition.)

15 Case control or cohort studies or other
16 types of epidemiologic studies.

17 So, for instance, in this guideline I
18 believe it says that for antibiotic prophylaxis to
19 dosing for obese patients, even though there is
20 excellent pharmacologic data to show that if you're
21 morbidly obese or obese you need a higher dose of
22 the prophylactic antibiotic -- antibiotic in this they
23 give it an unresolved issue because there's not a
24 randomized control trial actually done in patients
25 showing that. Makes no sense, but that's what

1 they've decided to do.

2 Q. I'm a little confused. Did -- under the
3 GRADE approach, epidemiologic studies that are not
4 randomized control studies can be considered as
5 evidence?

6 A. Well, the GRADE -- I'm not that familiar
7 with the grading. But I think the GRADE system
8 first gives a grade for different types of studies.
9 So you have randomized control trials, metaanalysis,
10 systematic reviews, case control, cohort studies,
11 all the different types of epidemiologic studies and
12 then grades them from highest to lowest. And then
13 within those they talk about a variety of factors:
14 Power, intrinsic biases, other types of biases that
15 might be. And so they come up with ultimate score
16 for various types of publications. So when they do
17 their review, they then put each of these papers
18 into little boxes. And at least from what I
19 understand the decision was made on this specific
20 guideline to only include randomized control trials
21 and systematic reviews and metaanalyses.

22 Q. So no epidemiologic data was included?

23 A. Well --

24 MR. B. GORDON: Object to form.

25 BY MR. C. GORDON:

1 Q. As you understand it.

2 MR. B. GORDON: Misstates testimony.

3 THE WITNESS: That would be epidemiologic
4 data. But other types of epidemiologic data would
5 be excluded.

6 BY MR. C. GORDON:

7 Q. Is it your understanding it would have
8 excluded any cohort studies; is that right?

9 A. Correct. But they were not randomized
10 control. Yup.

11 Q. Or case control studies?

12 A. Correct.

13 And it's just one approach. If you look
14 at the Society for Healthcare Epidemiology of
15 America that put out a compendium of recommendations
16 or if you look at the Association for Professionals
17 in Infection Control or if you look in fact at
18 surgical societies, they don't take that approach.
19 So there are various approaches to development of
20 guidelines.

21 MR. C. GORDON: Let me show you Exhibit 7.

22 (Exhibit 7 marked.)

23 BY MR. C. GORDON:

24 Q. And my understanding is that Exhibit 7 is
25 additional material that has been published by the

1 CDC online as the supporting documentations
2 supporting backup for Exhibit 6; correct?

3 A. Basically a supplement, yes.

4 Q. Have you seen Exhibit 7 before? Either
5 online or in hard copy?

6 A. Yes.

7 Q. And in connection with rendering your
8 opinion here, did you have occasion to consult any
9 of the supplementary online content in Exhibit 7?

10 A. Yes.

11 Q. When did you do that?

12 A. The specific online supplement material
13 came out about the same time this guideline was
14 published. But there was drafts of that guideline a
15 number of -- not even months -- it may have been a
16 year before. So I have reviewed the draft guideline
17 and written public -- there's a public comment
18 period and -- written comments about the guideline.
19 That was probably a year or two ago. I don't
20 remember. I don't believe all of this material was
21 available at that specific time. This came out
22 about the same time the guideline came out.

23 Q. Okay. And I want to direct your attention
24 to page 7 of Exhibit 7. Under section "3.2.
25 Literature Search." And the second full paragraph

1 where it says "Initial searches were designed to
2 identify systematic reviews (SRs) and randomized
3 controlled trials (RCTs). SRs that included
4 non-randomized trials and observational studies
5 (OBs) were eligible for inclusion. Three factors
6 influenced the decision to limit literature searches
7 to RCTs and SRs." And then it goes on to describe
8 the reasons.

9 But would -- is that consistent with your
10 understanding of what the systematic review approach
11 used by the CDC for the 2017 systematic review
12 prevention guideline was?

13 A. Well, I would say that was the systematic
14 review for this specific guideline --

15 Q. Yes --

16 A. -- not all.

17 Q. -- that's what I want to ask.

18 A. Not all guidelines that CDC does or all
19 guidelines that this division does. As I say, it
20 basically evolves with changes with the guideline.

21 The other factor that was interesting was
22 that they also decided that they would end their
23 review in December of 2011 even though this
24 guideline was being written in 2017. So that meant
25 any randomized controlled trials, systematic

1 reviews, or metaanalyses that were published between
2 December '11 and May of 2017 were ignored.

3 Q. Okay. So in terms of what literature was
4 considered for the 2017 surgical site infection
5 guideline, is it your understanding that the CDC
6 limited that search to systematic reviews which may
7 have included randomized trials -- non-randomized
8 trials and observational trials and randomized
9 control trials?

10 A. Can you read that back? That was kind of
11 long.

12 (Record read as follows:

13 "Q. So in terms of what literature was
14 considered for the 2017 surgical site
15 studies [sic] guideline, is it your
16 understanding that the CDC limited that
17 search to systematic reviews which may
18 have included randomized trials --
19 non-randomized trials and observational
20 trials and randomized control trials?")

21 THE WITNESS: I'm going to need you to
22 reword that because --

23 MR. C. GORDON: Yeah.

24 THE WITNESS: -- it doesn't make any
25 sense.

1 MR. C. GORDON: That's fair.

2 Q. Earlier I thought you said that the CDC
3 limited -- was limiting its systematic reviews, not
4 only randomized control trials; right?

5 THE REPORTER: "Not only randomized
6 control..."?

7 MR. C. GORDON: "Trials now; correct?"

8 THE WITNESS: Well, I said randomized
9 control trials, systematic reviews, and metaanalyses.

10 MR. C. GORDON: Oh, you did? Okay. I'm
11 sorry if I misstated.

12 MR. B. GORDON: Several times.

13 BY MR. C. GORDON:

14 Q. So this is consistent then with what
15 you're saying; randomized control trials, systematic
16 reviews, and metaanalyses?

17 A. Correct.

18 Q. That is different than what you did in
19 coming up with the 1999 surgical site infection
20 guidelines; right?

21 A. Correct. More limited.

22 Q. The current standard that the CDC applied
23 for the 2017 surgical site infection guidelines was
24 more limited?

25 A. Correct.

1 Q. So going back to your statement in your
2 expert report that you applied the methodological
3 gold standard -- CDC methodological gold standard,
4 that would be the standard that you were employing
5 in 1999 when you came up with the surgical site
6 infection guideline; is that right?

7 A. More inclusive, yes, correct.

8 Q. Not the current 2017 guideline?

9 A. Correct.

10 Q. And are there any studies that directly
11 address the issue of anything related to
12 specifically Bair Hugger in surgical site infections
13 that you relied on in your report that would have
14 passed muster under the current CDC surgical site
15 infection guideline standard?

16 A. Well, I guess it would depend on how you
17 define "pass muster." That there would be --

18 Q. Any randomized control trials.

19 A. There would be one randomized control --
20 well, the answer to that is in prosthetic joint
21 infections, the answer is no.

22 Q. Okay. How about a metaanalysis or
23 systematic review?

24 A. Well metaanalyses and systematic reviews
25 are often also just limited to randomized control

Page 66

1 trials. And the answer to that would be no. But
2 prosthetic joint infections, no. There are no data
3 that I'm aware of documenting an efficacy or
4 normothermia or the efficacy of Bair Hugger in
5 preventing infections in prosthetic joint
6 infections.

7 Q. My question is whether Bair Hugger causes
8 or contributes to peri-prosthetic joint infections.
9 Are there any randomized control trials that you're
10 aware of?

11 A. That's what I just said.

12 MR. B. GORDON: Object to form.

13 BY MR. C. GORDON:

14 Q. No. You were talking about normothermia.
15 I'm -- I'm -- my question's about -- the allegations
16 in this lawsuit, you understand the plaintiffs are
17 alleging that the Bair Hugger caused their
18 peri-prosthetic joint infections; right?

19 A. Correct.

20 Q. And your opinion is basically yes, that's
21 correct; right?

22 A. Correct.

23 Q. And my question is under the current
24 standards employed by the CDC for the development of
25 the 2017 surgical site infection guidelines limiting

Page 67

1 to randomized control trials, metaanalyses, and --

2 MR. B. GORDON: Systematic review.

3 BY MR. C. GORDON:

4 Q. -- systematic reviews, are there any --
5 let's start with the randomized control trials --
6 any randomized control trial upon which you relied
7 for your conclusion that Bair Hugger causes surgical
8 site infections?

9 And just to be clear. When I -- I'm going
10 to -- I may slip and say "surgical site infections."
11 When I'm talking specifically about the lawsuit or
12 the Bair Hugger in this context, I'm really talking
13 about the allegations of the plaintiffs relating to
14 peri-prosthetic joint infections. Okay? I'll try
15 to say PJI to be clear. But if I slip, you may want
16 to call me on it.

17 Are you aware of any -- do you cite or
18 rely on any randomized control trial that you
19 contend demonstrates that the Bair Hugger causes
20 PJIs?

21 A. There are no randomized control trials,
22 systematic reviews, or metaanalyses documenting
23 either the efficacy of Bair Hugger and preventing
24 any complications in prosthetic joint infection or
25 in prosthetic joint surgery patients or any

Page 68

1 randomized control trials, metaanalyses, systematic
2 reviews documenting complications associated with
3 Bair Hugger and prosthetic joint infections. There
4 are no randomized control trials in prosthetic joint
5 infections involving Bair Hugger.

6 Q. Okay. So your answer would be there
7 are -- there -- there is no evidence in the medical
8 literature that would meet the current criteria for
9 the CDC surgical site infection guidelines?

10 MR. B. GORDON: Objection to form; asked
11 and answered. Misstates the witness' testimony.

12 THE WITNESS: I'd say again that this
13 methodology and approach was specific to this
14 guideline and for very specific procedures. So it
15 was not a revision of the entire surgical site
16 infection guideline from 1999. But there were no
17 randomized control trials, as I say, showing
18 efficacy or detriment of the Bair Hugger in terms of
19 prosthetic joint infections.

20 BY MR. C. GORDON:

21 Q. I noticed on your list of "Additional
22 Materials Reviewed" that you got Sikka 2014. Do you
23 recall reading that?

24 A. Vaguely.

25 Q. Do you know if that was one you recall you

Page 69

1 reviewed before or after your opinion?

2 A. I believe it was before.

3 Q. Do you recall if that was a systematic
4 review of all the literature available on --

5 A. I'd have to --

6 Q. -- whether forced air warming increases
7 the risk of PJIs?

8 A. I would have to look at it. It's been
9 awhile.

10 MR. B. GORDON: Corey, when you get to a
11 good point, it might be a good time to take a break
12 in a bit. My bladder is getting there.

13 MR. C. GORDON: Sure.

14 THE WITNESS: So excuse me. Your question
15 again was?

16 BY MR. C. GORDON:

17 Q. Is the Sikka paper a systematic review?

18 A. Well, he doesn't really say. He has -- he
19 basically has no methodology here. He says, "The
20 purpose of the present manuscript is to review the
21 current literature on the use of patient warming
22 devices in orthopedic surgery specifically to joint
23 arthroplasty. It never says what he did, how he did
24 it, where he found them, how he evaluated them or
25 anything else.

1 Q. And those are, in your view, problems with
2 any kind of a published article; right?

3 A. Well, it would be nice if he had a
4 methodology. I'd like to see how he went about what
5 he did, number one, how he evaluated them, other
6 than his personal opinion.

7 I think the difference is that this --
8 this is a review. How systemic it is, I'd have to
9 look at more carefully to assess that.

10 Q. Where in your report do you explain your
11 methodology in how you selected articles other than
12 your own personal opinion?

13 A. I don't have a section where I say how I
14 did it.

15 Q. I guess now is your time. How did you do
16 it?

17 A. Mine is not a peer-reviewed paper though
18 which the editor should have asked for.

19 THE REPORTER: Which who should have asked
20 for?

21 THE WITNESS: Editor of the journal.

22 How I did it is -- as I said before, I
23 tried to do as systematic and broad a review using
24 Google search and PubMed for -- and using all
25 combinations that I can think of of Bair Hugger,

1 forced air warmers, normothermia, hypothermia,
2 surgical site infections, prosthetic joint
3 infections specific to total hip/total knee
4 arthroplasty procedures, et cetera, et cetera, as
5 broadly and as many times as I could.

6 Also, when I found articles, there's a
7 little link underneath PubMed where it says similar
8 articles, click on that. And also going through
9 those, trying to be as comprehensive as I could
10 possibly be.

11 BY MR. C. GORDON:

12 Q. But you excluded some articles; right?

13 A. I didn't exclude any articles. I may not
14 have included them in my report, as I mentioned
15 before. If I had a specific reference to data from
16 a paper, I referenced that paper. So you could go
17 look at it and say is Jarvis quoting that correctly
18 or not.

19 Q. Well, let's talk specifically about the
20 Cristina paper. You would agree, would you not,
21 that the Cristina paper is not consistent with what
22 you conclude on page 15.

23 MR. B. GORDON: Page 15 of his report?

24 BY MR. C. GORDON:

25 Q. Page 15 of your report, yes.

1 A. Page 15 of my report says, "Cumulatively,
2 these studies" -- "these" referring back to 1, 2, 3,
3 4, 5 studies -- "that show that airborne particle
4 counts and microbial CFUs can be elevated near or at
5 the operative/incision site and that activities that
6 increase the particle counts/microbial CFUs increase
7 the risk of SSL." And that is true.

8 Q. You would agree with me that the Cristina
9 paper would -- is not consistent with the other --
10 with -- well, certainly it's not consistent with the
11 Stocks paper that you cite there; right?

12 MR. B. GORDON: Object to form.
13 Mischaracterizes the evidence. The document speaks
14 for itself and addresses Stocks specifically.

15 MR. C. GORDON: That wasn't a speaking
16 objection, was it, Mr. Gordon?

17 THE WITNESS: Repeat your question again?

18 BY MR. C. GORDON:

19 Q. The Cristina paper that you reviewed and
20 excluded for the reasons you've talked about
21 earlier, that is -- has conclusions that are
22 inconsistent with the conclusions that you cite from
23 the Stocks paper; right?

24 MR. B. GORDON: Objection to form.
25 Mischaracterizes the evidence.

1 THE WITNESS: It -- I would word it
2 differently. I would say she came to different
3 conclusions using a different methodology.

4 BY MR. C. GORDON:

5 Q. Okay. And those different conclusions
6 using a different methodology, they differ from the
7 conclusions that Stocks, et al., came to; correct?

8 A. Correct.

9 Q. And you cited and relied on Stocks on page
10 15; correct?

11 A. One of five studies that I --

12 Q. Right.

13 A. -- reference, yes.

14 Q. Well, do any of the other studies that you
15 reference on page 15 address the issue of whether
16 particle counts correlate with bacterial CFU counts?

17 A. Well, Anderssen looked at both particle
18 counts and CFUs. Darouiche looked at CFUs. I can't
19 remember offhand if he looked at particle counts or
20 not.

21 Q. My question is very specific. Does
22 Andersson say anything about correlating the number
23 of particles with the number of bacterial CFUs?

24 A. Well, he was correlating more the CFU with
25 the amount of traffic.

Page 74

1 Q. I understand that. Does -- Anderssen
2 doesn't say anything about or even attempt to
3 determine whether there's a correlation between the
4 number of particles and the number of CFUs; correct?

5 A. Correct.

6 Q. Neither does Darouiche; right? It doesn't
7 correlate bacteria --

8 A. Right.

9 Q. -- and particles?

10 A. Correct.

11 Q. Nor does Lidwell or Edmonson; right?

12 A. Right.

13 Q. The only article --

14 THE REPORTER: "Nor does Lidwell..."

15 MR. C. GORDON: Lidwell.

16 THE WITNESS: Or Edmonson.

17 BY MR. C. GORDON:

18 Q. -- you cite for the proposition that the
19 number of particles that you can counts correlates
20 with the number of bacterial CFUs is the Stocks 2010
21 paper; right?

22 A. In the report, yes, correct.

23 Q. And the -- in the report?

24 A. In the report.

25 Q. "In the report." Sorry.

Page 75

1 And that's contrary to the conclusions
2 that Cristina came up with; right?

3 A. Right, using a different methodology.

4 Q. Right. And in your report you don't
5 take -- you don't mention the fact that there are --
6 that there's at least one contrary study to Stocks;
7 right?

8 MR. B. GORDON: Object --

9 THE WITNESS: Correct.

10 MR. B. GORDON: -- to the
11 characterization.

12 THE WITNESS: Correct. But I also don't
13 mention a number of other papers that show the same
14 thing.

15 MR. B. GORDON: If you're going to ask him
16 to characterize these studies, he may need to look
17 at these studies, Cory.

18 MR. C. GORDON: I understand.

19 Q. Well, tell me what other studies -- you
20 pulled out some notes apparently -- so what other
21 studies support the conclusion that measuring
22 particles is a valid surrogate for -- or it --
23 strike that.

24 Tell me what other articles you're --
25 you're referring to that support the conclusion that

Page 76

1 the count of particles is correlated with a --
2 bacterial CFUs?

3 A. Seal and Clark --

4 MR. B. GORDON: Seal and Clark.

5 THE WITNESS: -- Stocks, Raval --

6 BY MR. C. GORDON:

7 Q. How do you spell --

8 A. -- Birgand.

9 Q. What was the -- Raval?

10 A. R-A-V-A-L. And Birgand, B-I-R-G-A-N-D.

11 Q. Okay. Anything else?

12 A. No.

13 Q. And when did you review those -- well,
14 start with Seal and Clark. When did you review that
15 one? Before or after you wrote your report?

16 A. I couldn't tell you.

17 Q. How about Raval? When did you review
18 that?

19 A. I believe that was after.

20 Q. How about Birgand?

21 A. I can't recall.

22 MR. C. GORDON: Mr. Gordon -- Mr. Ben
23 Gordon needs a potty break. So we'll do that.

24 THE VIDEOGRAPHER: The time is 10:36 a.m.
25 We're off the record.

Page 77

1 (Recess taken from 10:36 a.m. to 10:57 a.m.)

2 THE VIDEOGRAPHER: This marks the
3 beginning of Volume I, file 2 in the deposition of
4 Dr. William Jarvis. The time is 10:57 a.m. We're
5 on the record.

6 BY MR. C. GORDON:

7 Q. Dr. Jarvis, the Stocks study that you cite
8 on page 15, that found a correlation between
9 particles and CFUs, do you recall that paper?

10 A. Yes.

11 Q. Do you recall the size of the particles
12 that the Stocks group found correlated with CFUs?

13 A. (Witness reviews document.)

14 Can you read that back.

15 (Record read as follows:

16 "Q. Do you recall the size of the
17 particles that the Stocks group found
18 correlated with CFUs?")

19 THE WITNESS: Well, first -- and, again,
20 in comparing to the Cristina paper, they looked at
21 particle diameters of a much wider range. So .3,
22 less than .5 microns. .5 -- less than .5 or equal
23 to 1. 1 to 3 microns. 3 to less than 5. And then
24 5 to 10 microns.

25 Now, the particle size that they at least

Page 78

1 describe in terms of correlation is a 10-micron
2 particle.

3 BY MR. C. GORDON:

4 Q. What about the others micron sizes? Do
5 they find a correlation?

6 A. Well, it looks like the P value of greater
7 or equal to 10 microns is .001. 5 to 9.99 microns
8 is .015. And 3 to 4.9 is 0.56.

9 The smaller, 0.3 to .49 is .23. 0.5 to
10 0.99 is .24. And 1 to 2.9 is .47.

11 Q. So you would agree -- so below 5 microns
12 there was no correlation between particles; is
13 that --

14 A. Well, 3 --

15 MR. B. GORDON: Object to form.

16 THE WITNESS: 3 to 4.9 is 0.56 [sic].

17 That's pretty close.

18 (Reporter asks for repetition.)

19 THE WITNESS: 3 to 4.9 microns, P value is
20 0.056.

21 BY MR. C. GORDON:

22 Q. Oh, you said "0.56." 0.056?

23 A. Yes, sir.

24 Q. That's technically not statistically
25 significant though; right?

Page 79

1 A. Well, you have to look at the data and
2 look at the distribution and look at the 95 percent
3 confidence interval. And it's close.

4 THE REPORTER: "And look at the?"

5 THE WITNESS: 95 percent confidence
6 interval.

7 So it's close, but it's not, according to
8 this, statistically significant.

9 BY MR. C. GORDON:

10 Q. Okay. And certainly below 3 microns,
11 there's no correlation whatsoever; right?

12 A. In this particular study, correct.

13 Q. That's the only study you cite for
14 correlation between particles and bacteria; right?

15 A. Well, actually the Darouiche study does as
16 well.

17 Q. How does Darouiche correlate the number of
18 particles and the number of bacterias -- bacteria?

19 A. Let me see if I have it. If I don't I'll
20 borrow yours, if you don't mind.

21 (Witness reviews document.)

22 Could you read the question back again.

23 (Record read as follows:

24 "Q. How does Darouiche correlate the
25 number of particles and the number of

Page 80

1 bacteria?")

2 THE WITNESS: Well, they looked at
3 particle densities as particles per cubic meter and
4 had several size thresholds: 0.3 microns,
5 0.5 microns, 1 micron, 5 microns and greater/equal
6 to 10 microns. And then they have a Figure 5 which
7 shows a total particulates per meter cubed versus
8 CFU per meter cubed.

9 BY MR. C. GORDON:

10 Q. Was the purpose of the study to try and
11 determine whether there was a correlation between
12 particle size and CFUs?

13 A. Obviously that was one of the purposes of
14 the study. There were multiple purposes of the
15 study. The study was to look at particulates. It
16 was also to look at CFUs. It was also to look at
17 SSIs and primarily randomized control trials. And
18 one of the only randomized control trials here --
19 (Reporter asks witness to slow down.)

20 One of the only randomized -- well, the
21 only randomized control trial in these five studies,
22 it was particularly looking at a device that would
23 remove particulates, and presumably therefore CFUs
24 as well, from the operative site and its impact on
25 surgical site infection.

Page 81

1 It showed that as they decreased
2 particulates and as they decreased CFUs, they saw a
3 significant reduction not in superficial incisional
4 SSIs -- which you would think, according to
5 Dr. Wenzel's study that you would see -- didn't see
6 that. But what you did see was by removing the
7 particles in the CFUs from the air over the surgical
8 wound, that you would decrease deep surgical wound
9 infections.

10 Q. The particles and the CFUs were being
11 removed simultaneously; right?

12 A. Correct.

13 Q. By a device called a Nimbic system; right?

14 A. I don't remember the name of the device
15 but basically an air-sucking device that would
16 remove particles. And some of those particles have
17 CFUs.

18 Q. By the way, did you know that Dr. Stocks
19 was a shareholder in the company that makes the
20 Nimbic system?

21 A. Dr. Stocks?

22 MR. B. GORDON: Object to form.

23 BY MR. C. GORDON:

24 Q. Yeah, Dr. Stocks.

25 MR. B. GORDON: Lacks foundation.

1 THE WITNESS: No. I'm not sure how that
2 has any influence on anything, but fine.

3 BY MR. C. GORDON:

4 Q. Dr. -- so the Darouiche study using this
5 localized air filtration system was filtering both
6 particles and CFUs; right?

7 A. Correct.

8 Q. It wasn't independently assessing whether
9 in the absence of this device where they're removing
10 both simultaneously particles and CFUs existed and
11 moved up or down as -- in any correlation. It's
12 completely different than the way the Stocks paper
13 tried to correlate bacteria and CFUs --

14 MR. B. GORDON: Object to the form of the
15 question.

16 BY MR. C. GORDON:

17 Q. -- right?

18 A. I don't know that I would agree with that.

19 They're both looking at -- at the fact
20 there are particulates in the air. And some of
21 those particulates in the air are either bacteria or
22 particulates carrying bacteria. And one of the
23 questions that is raised by Stocks as well as
24 Darouiche is could you just measure particulates?
25 Because particulates are much easier to measure.

1 multiple results in the paper. Obviously the
2 results in the paper are what they decided to study.
3 They wouldn't have a result in a paper if they
4 didn't want to study it. So obviously showing a
5 correlation as they do in Figure 5 between
6 particulates and CFU was a part of the study. They
7 obviously did those measurements for a reason.

8 BY MR. C. GORDON:

9 Q. Did Darouiche, et al. conclude that there
10 was a correlation between particulates and CFUs?
11 Not your interpretation of a diagram --

12 MR. B. GORDON: Objection --

13 BY MR. C. GORDON:

14 Q. -- did they conclude that?

15 MR. B. GORDON: -- argumentative.

16 THE WITNESS: Well, it's not my
17 interpretation of the diagram. When you publish a
18 paper you have results in that paper. And one of
19 the parts of my systematic review is to look
20 critically and evaluate all of the data in the
21 paper, not just some of the data in the paper, and
22 see if I agree with what they conclude.

23 Let me see what he says.

24 MR. B. GORDON: By the way, Corey, there's
25 no accent on the u. His name is -- is it pronounced

1 One of the reason why I refer to the Raval study is
2 it is a realtime method for determining bacterial
3 count. So it kind of moves to the next level.

4 But before you have that with something
5 like polymerase chain reaction or another type of
6 molecular diagnostic test that could be realtime,
7 you -- if you were looking for bacteria, you have to
8 do cultures. And that takes days. So you get an
9 answer, you know, three days from now, four days
10 from now.

11 So one of the advantages of measuring
12 particulates is you can do that with a laser
13 particulate counter immediately. So if there is a
14 correlation which Stocks and in a randomized control
15 trial Darouiche shows, then you can measure
16 particulates and extrapolate or correlate that with
17 colony-forming units or bacterial contamination.

18 Q. Okay. And just so we're clear, your
19 interpretation of the Darouiche study is that it was
20 specifically looking at the question of whether you
21 could just measure particulates and thereby get an
22 idea of how many bacteria would be present?

23 MR. B. GORDON: Object to form. Misstates
24 the witness' testimony. Argumentative.

25 THE WITNESS: Yeah, as I said there were

1 "Dar-u-shay"?

2 MR. C. GORDON: I have no idea.

3 MR. B. GORDON: Okay. I thought maybe we
4 left the accent on the U off.

5 MR. C. GORDON: "Da-roosh." I'm sorry.

6 MR. B. GORDON: I've been looking for a
7 long time when I was pronouncing it. I thought
8 maybe you put that in personally.

9 MR. C. GORDON: No.

10 MR. ASSAAD: Da-veed [phonetic], David
11 (laughter).

12 MR. C. GORDON: Well --

13 MR. B. GORDON: I'm just curious.

14 MR. C. GORDON: -- "Da-veed" was not
15 pronounced that way in Israel.

16 MR. ASSAAD: Or in France?

17 MR. C. GORDON: Hmm?

18 MR. ASSAAD: In France it would be
19 "Da-veed."

20 MR. C. GORDON: No. Well --

21 MR. ASSAAD: It would be. It's a big
22 world out there.

23 THE WITNESS: Well, since his -- his
24 bottom-line outcome that he was mostly interested in
25 was SSIs, most of his discussion -- virtually all of

1 his discussion really focuses on surgical site
2 infections and the fact that there are CFU counts
3 elevated at the surgical site, when there are more
4 people in the room, when there's more activity. And
5 that this device removes them and it removes SSIs.

6 So he doesn't really address the particle
7 count correlation with CFUs. But obviously that
8 figure is in the table -- in the paper showing a
9 correlation.

10 (Exhibit 8 marked.)

11 BY MR. C. GORDON:

12 Q. Showing you Exhibit 8. Is this the Seal
13 and Clark article you referred to earlier?

14 A. Yes.

15 Q. If you could turn to page 29 -- 229 of
16 this under discussion. The second full paragraph,
17 second sentence. "For the ultra-clean theatre the
18 statistical analysis shows there is a significant
19 relationship between particles in the size range
20 5.0-7.0 microns and the BCP counted." I think it's
21 bacterial -- bacterial-containing particles --
22 bacteria-containing particles. Sorry.

23 MR. B. GORDON: Is there a question?

24 BY MR. C. GORDON:

25 Q. Did I read -- well, first of all, do you

1 see that, where I read?

2 A. I believe so.

3 Q. And then they go on to conclude, "This
4 demonstrates that counts of particles in the size
5 range 5.0 7.0 microns may well provide a valid
6 alternative to BCP counts as an indication of
7 bacterial contamination in the vicinity of the
8 operating site" -- "operation site in the ultraclean
9 theatre [as read]."

10 Did I read that correctly?

11 MR. B. GORDON: No. Objection. You left
12 out the word "airborne."

13 BY MR. C. GORDON:

14 Q. "Airborne"?

15 MR. B. GORDON: You don't like that word,
16 I know.

17 MR. C. GORDON: No, I'll read it again.

18 MR. B. GORDON: Please do.

19 MR. C. GORDON: I didn't mean to --

20 "This demon- --"

21 MR. B. GORDON: I know you don't like
22 "airborne."

23 BY MR. C. GORDON:

24 Q. "This demonstrates that counts of
25 particles in the size range 5.0-7.0 microns may well

1 provide a valid alternative to BCP counts as an
2 indication of airborne bacterial contamination in
3 the vicinity of the operation site in the ultraclean
4 theatre."

5 Did I read that correctly?

6 A. I believe so.

7 Q. And if you jump to the bottom of the next
8 paragraph, there's a sentence where they say,
9 "Particles less than 3 microns and greater than
10 15 microns clearly corresponded with activity even
11 when bacteria were not detected."

12 Did I read that correctly?

13 MR. B. GORDON: For the record I'm going
14 to object to your -- to use your phrase --
15 cherry-picking sentences out of a study that he may
16 need to review more context.

17 MR. C. GORDON: Sure.

18 Q. Did I read that sentence correctly?

19 A. I believe so. It took me a while to find
20 it, but I think so.

21 Q. Then if you drop down to the -- towards
22 the bottom of the next paragraph, it says, "Particle
23 concentration levels measured at 0.5-3.0 microns and
24 greater than 15 microns in the turbulently
25 ventilated theatre showed less relation to activity

1 than those in the ultra-clean system."

2 And then they go on to say "Because of the
3 background effect of non-bacteria-carrying
4 particles, we cannot recommend this alternative for
5 bacteria counting in turbulently ventilated
6 conditions."

7 Did I read that correctly?

8 A. You read that correctly.

9 Q. So Seal and Cro- -- I almost said Seals &
10 Croft -- Seal and Clark you would agree -- as did
11 Stocks -- or -- yeah, Stocks -- looked at
12 different-sized particles; right?

13 A. I'd have to see what particle size they
14 looked at. They looked at 8 size ranges between 0.5
15 and 20 microns in Seal and Clark. So there's some
16 overlap. It didn't look exactly the same.

17 Q. Right. But would you agree that both
18 Stocks and Seal and Clark ultimately concluded that
19 whether -- whether in general you could correlate
20 particles and bacterial counts depended on the size
21 of the particles?

22 MR. B. GORDON: Object to the
23 characterization for the record.

24 THE WITNESS: I guess I'd say that they
25 found that certain particle sizes correlated in the

1 specific studies that they did under the
2 circumstances they did with the methodologies that
3 they used to test.

4 BY MR. C. GORDON:

5 Q. And certain particle sizes didn't
6 correlate; correct?

7 A. In those studies, correct.

8 Q. Right. And the ones that didn't
9 correlate, in both studies were small particles;
10 right?

11 A. Very small particles.

12 MR. B. GORDON: Object to form.

13 MR. C. GORDON: "Very small particles."
14 (Reporter asks for repetition.)

15 BY MR. C. GORDON:

16 Q. And the ones that they found didn't
17 correlate were small particles?

18 A. No, it's not --

19 MR. B. GORDON: Objection; "very small."

20 BY MR. C. GORDON:

21 Q. (Addressing the reporter) And he said
22 "very small particles."

23 A. Very small. So less than .5 microns.

24 Q. Less than .5 microns. Okay.

25 And -- well, where do you -- I'm sorry.

1 Where do you find either Stocks or Seal and Clark
2 finding a correlation between .5 and 3 microns, say?

3 A. On page 229 of the third paragraph it
4 says, "It has been shown previously in an ultraclean
5 theatre that measurement of particles in the 0.5 to
6 5-micron range gave peaks that correlated with
7 airborne bacteria during the description of the
8 ultra-clean conditions with the arrival and removal
9 of the patient."

10 And they reference themselves, Seal 1985.

11 Q. And you interpret the peaks as indicating
12 that whenever you've got -- that they concluded that
13 whenever you got these sized particles present, that
14 that correlates with bacteria?

15 A. That's what they're saying. I'm not
16 saying it; they're saying it.

17 Q. Okay. They also found that -- Seals [sic]
18 and Clark also concluded that there's a background
19 effect of non-bacteria-carrying particles in a
20 turbulent- -- ventilated turbulently theatre and
21 they don't recommend counting particles as a
22 surrogate for bacteria; right?

23 MR. B. GORDON: Objection; asked and
24 answered.

25 MR. ASSAAD: What page?

1 MR. B. GORDON: 229. That last sentence
2 he read.

3 THE WITNESS: Well, they point out that
4 samples in ultraclean system would be more sensitive
5 to transient concentration levels produced by
6 activity than that in a turbulent.

7 BY MR. C. GORDON:

8 Q. They specifically say that in a turbulent
9 system they don't recommend using particle counting
10 as a surrogate for bacteria; right?

11 MR. B. GORDON: Objection to form.
12 Misstates the evidence.

13 THE WITNESS: Well, they say particle
14 concentration levels measured at 0.5 to 3 microns
15 and greater than 15 microns in the turbulent
16 ventilated theatre showed less relation to activity
17 than those in the ultraclean system. The use of
18 multiple-point sampling rather than single-point
19 sampling that they used might give more accurate and
20 consistent results. So they're saying that perhaps
21 a different methodology would be better in that
22 situation.

23 BY MR. C. GORDON:

24 Q. And what's the next sentence?

25 A. And then because of the background effect

1 of non-bacteria-carrying particles, we cannot
2 recommend this alternative for bacterial counting in
3 turbulent ventilation conditions. But they haven't
4 provided any data to support that statement for the
5 alternative. If they're talking about alternative
6 bacterial counting being -- rather than using single
7 point, using multiple point they don't provide any
8 data to support that.

9 Q. Okay. But this -- so Seal and Clark,
10 that's another study now that you say supports your
11 conclusion that whenever you've got particles, you
12 can assume there are bacteria there?

13 MR. B. GORDON: Object to the form.

14 THE WITNESS: Well, that misstates what
15 I've said. I said they are authors that have done a
16 study that have shown a correlation between
17 particulate counts and CFUs, which is true. What
18 they say is that they -- that their findings were
19 stronger in a non-turbulent setting than a turbulent
20 air setting. But they found a correlation.

21 BY MR. C. GORDON:

22 Q. You can't point to a single study that
23 demonstrated that the Bair Hugger increased
24 bacterial CFUs in the vicinity of the surgical site;
25 correct?

Page 94

1 MR. B. GORDON: Objection to form.
2 Misstates his testimony and the evidence. Asked and
3 answered.

4 THE WITNESS: That the Bair Hugger
5 increases particulates in the sterile field?

6 MR. C. GORDON: No, that's not what I
7 asked, sir.

8 Read my question back, please. Maybe Mr.
9 -- maybe both of you misheard it. I think I was
10 rather precise.

11 (Record read as follows:

12 "Q. You can't point to a single study
13 that demonstrated that the Bair Hugger
14 increased bacterial CFUs in the vicinity
15 of the surgical site; correct?")

16 MR. B. GORDON: Note the same objection,
17 please.

18 THE WITNESS: I'm trying to think if I
19 have seen a study that looked specifically at that.
20 Certainly we've seen studies that show that the
21 intake air is not sterile; that the exhaust -- the
22 air coming out is contaminated; the cultures of both
23 intake and outtake lines are often culture-positive;
24 that the filter used is inadequate; and that air
25 even comes around the filter and doesn't go through

Page 95

1 the filter.

2 But specifically looking at CFU, I know
3 there are a number of studies looking at increased
4 particulate counts; I don't think any of them
5 specifically looked at CFUs.

6 BY MR. C. GORDON:

7 Q. Are you aware of any studies that have
8 looked at CFUs and found that there was no increase
9 attributable to the Bair Hugger?

10 A. I'm trying to think. There may be a
11 couple of very small studies -- like, you know, five
12 patients -- that may have looked at that.

13 Q. And the -- the studies that you cite for
14 the increase in particulate matter, how many
15 patients did they involve?

16 A. I'd have to go back and look at the
17 specific papers. There's two, three, four -- at
18 least six of them. I can't remember offhand.

19 Q. Tell me -- tell me what you're counting as
20 the six papers that show an increase in particle
21 size.

22 MR. B. GORDON: Objection; form.

23 THE WITNESS: What I said is --

24 BY MR. C. GORDON:

25 Q. An increase in particle counts.

Page 96

1 (Reporter asks for repetition.)

2 An increase in particle counts.

3 A. So studies that showed the Bair Hugger
4 increases particle counts in the sterile field would
5 include Leaper, McGovern, Lague [phonetic], Reed,
6 Tsai --

7 MR. B. GORDON: T-S-A-I.

8 MR. C. GORDON: T-S-A-I.

9 THE WITNESS: And Albrecht.

10 MR. B. GORDON: A-L-B-R-E-C-H-T.
11 BY MR. C. GORDON:

12 Q. Putting aside the Tsai one for a second --
13 I'll ask you about that separately -- those other
14 five, did they involve a single patient?

15 A. I'd have to go back and look at each of
16 those specific studies to answer that. At least
17 McGovern did.

18 Q. McGovern involved patients?

19 A. Well, there were multiple parts to his
20 paper.

21 Q. I'm talking about studies that showed --
22 that you're relying on for the notion that Bair
23 Hugger increases particles at the surgical site.

24 MR. B. GORDON: Objection to form. That's
25 what you should have asked.

Page 97

1 THE WITNESS: Well, what I --
2 (Reporter asks for repetition.)

3 MR. B. GORDON: Then that's what you
4 should have asked.

5 MR. C. GORDON: That is what I asked.
6 That's exactly what I asked.

7 THE WITNESS: No, you said Bair Hugger
8 increased particle counts.

9 BY MR. C. GORDON:

10 Q. Following on the heels of my -- well,
11 okay.

12 Fine. Do any of those --

13 A. And all of those --

14 Q. -- do any of the studies that show an
15 increase in particle counts anywhere involve
16 patients?

17 A. Well, as I say, McGovern had multiple
18 components to a study. And I would have to look at
19 the others.

20 (Mr. Boone joined proceedings.)

21 Q. Okay. And do you recall as you sit here
22 right now what McGovern component -- first of all,
23 do you recall how McGovern came to the conclusion
24 that Bair Hugger increased particles?

25 A. I believe it was the bubble study.

1 Q. Yeah. Okay.
 2 (Reporter asks for repetition.)
 3 Q. The bubble study.
 4 A. Bubble.
 5 Q. Did the bubble study involve a single
 6 patient?
 7 A. No.
 8 Q. Okay. So did any of those studies involve
 9 a single patient --
 10 MR. B. GORDON: Objection; asked and
 11 answered.
 12 BY MR. C. GORDON:
 13 Q. -- those five studies?
 14 A. Well, as I said, I'd have to go look at
 15 these each of those studies specifically to answer
 16 that question.
 17 Q. You're not sure -- right? -- as you sit
 18 here?
 19 A. No, I'd have to look at the papers.
 20 Q. So if I were to tell you that not a single
 21 one of them involved so much as a single patient,
 22 you're -- you would say that you're not -- that
 23 that's not consistent with what you're recalling;
 24 you'd have to go back and check?
 25 MR. B. GORDON: Objection; argumentative.

1 Q. But it's okay for you to rely on studies
 2 that show increased particles with not a single
 3 patient; right?
 4 MR. B. GORDON: Objection; form.
 5 Argumentative.
 6 THE WITNESS: Well, you're looking at --
 7 at something that's different. My point with the
 8 other was not that there's a patient or there's not
 9 a patient. My point was that the number of
 10 measurements being done was small.
 11 If you're looking for CFUs and I put an
 12 agar plate out here and I leave it out there for a
 13 minute, probably not going to have anything on it.
 14 If I leave it out there for a day or if I do a
 15 hundred of them, I'm much more likely to detect some
 16 CFUs.
 17 So it more had to do with the study design
 18 than how many patients were there.
 19 BY MR. C. GORDON:
 20 Q. So good study design, you would agree,
 21 would have agar plates and active sampling; right?
 22 MR. B. GORDON: Objection to form.
 23 THE WITNESS: Don't know how you're
 24 defining active sampling. If you mean active air
 25 sampling?

1 Asked and answered.
 2 THE WITNESS: Well, I don't know that I
 3 would word it that way. I'd like to look at those
 4 papers and confirm that, number one.
 5 And, number two, the fact that they show
 6 that increased particulates occurred with or without
 7 a patient -- you know, we're talking about the Bair
 8 Hugger. Does a Bair Hugger produce particles that
 9 end up over the operative field. If you have a
 10 patient there, obviously you have an increased risk
 11 of an infection.
 12 BY MR. C. GORDON:
 13 Q. When I asked you about studies that show
 14 that the Bair Hugger -- that looked at the number of
 15 bacteria that might be deposited at the surgical
 16 site when the Bair Hugger was used, you said well,
 17 those studies were small; they involved only a
 18 few -- five patients or so.
 19 MR. B. GORDON: Objection --
 20 BY MR. C. GORDON:
 21 Q. Do you remember that?
 22 MR. B. GORDON: Objection to form.
 23 THE WITNESS: I remember something like
 24 that, yes.
 25 BY MR. C. GORDON:

1 BY MR. C. GORDON:
 2 Q. Active air sampling. Like with an
 3 Anderssen sampler?
 4 A. That would be a good way to do it, yes.
 5 Q. Okay. That's exactly how Cristina did it;
 6 right?
 7 A. Well, she did it, yes, that way. But she
 8 also had an electronic scalpel going on at the time.
 9 And that's really when she saw her particle count
 10 increase.
 11 Q. Are electronic scalpels used in orthopedic
 12 implant surgery?
 13 A. Some probably use it. And they use it for
 14 a limited period of time, in contrast to the Bair
 15 Hugger that's on the entire time. So it's a very
 16 different situation.
 17 Q. They -- and in joint implant surgery, do
 18 they use electric drills?
 19 A. Usually, yes.
 20 Q. How about saws?
 21 A. Yes.
 22 Q. How about diathermy equipment?
 23 A. I'm not sure about that.
 24 Q. Have you ever heard of something called a
 25 Bovie?

Page 102

1 A. Yes.
 2 Q. What is a Bovie?
 3 A. Basically it's a way to cauterize tissue
 4 or vessels or blood.
 5 Q. An electric cauterizing tool?
 6 A. Correct.
 7 Q. And you've never heard that referred to as
 8 a diathermy tool or --
 9 A. No, I usually hear the word Bovie.
 10 Q. Okay. Does -- and are Bovies routinely
 11 used during implant surgery?
 12 A. Routinely they're not used consistently
 13 and constantly like a Bair Hugger. They are used
 14 intermittently like a zzt [phonetic] and stop. So
 15 it's probably -- total time that it's used is maybe
 16 less than 5 or 10 minutes in the entire procedure.
 17 Q. Does the use of the Bovie generate
 18 bio-aerosols?
 19 A. It probably depends on what you're putting
 20 the Bovie next to.
 21 Q. Inside a patient.
 22 A. It can.
 23 Q. How about drills? Do they generate
 24 bio-aerosols when they are drilling into a patient?
 25 A. They can.

Page 104

1 THE WITNESS: No. I've actually done
 2 Medline searches on all of those. And there's no
 3 correlation between any of those and infection.
 4 Unlike the Bair Hugger.
 5 BY MR. C. GORDON:
 6 Q. Have you seen any studies that have looked
 7 at impact of use of those -- any of those types of
 8 devices on the health of the healthcare workers?
 9 A. Well, we're not really talking about
 10 health of healthcare workers, are we? We're talking
 11 about infections in prosthetic joint patients.
 12 That's very different.
 13 Q. And you've seen -- you're saying you've
 14 seen studies that have actually looked -- cor- --
 15 you have attempted to determine whether use of a
 16 drill or a saw, or a Bovie increases surgical site
 17 infections?
 18 MR. B. GORDON: Objection to form.
 19 Misstates what he said.
 20 THE WITNESS: I've done Medline searches
 21 and Google searches with key words being Bovie, many
 22 of the other devices that you've talked about --
 23 saws, drills, et cetera -- and surgical site
 24 infections. And for most of those, nothing comes
 25 up.

Page 103

1 Q. How about saws? Do they generate
 2 bio-aerosols when they're sawing into a patient?
 3 A. Well, I guess for all of these I would ask
 4 you what you mean by bio-aerosols. Are they
 5 producing microorganisms that are going to cause an
 6 infection? That's very different than are they
 7 producing smoke.
 8 Q. What does smoke consist of?
 9 A. Particles.
 10 Q. Well, isn't one of the premises of your
 11 opinion that particles equate to bacteria?
 12 MR. B. GORDON: Objection to form.
 13 Misstates his evidence -- testimony.
 14 THE WITNESS: I don't know I say they
 15 equate. They correlate with.
 16 BY MR. C. GORDON:
 17 Q. Okay. So --
 18 A. You know, of all the particles, some
 19 proportion of those particles are carrying bacteria.
 20 They're not all carrying bacteria.
 21 Q. Okay. So the particles that are being
 22 generated with the use of a Bovie or a drill or a
 23 saw, that's spewing out bacteria in your opinion
 24 right?
 25 MR. B. GORDON: Objection to form.

Page 105

1 BY MR. C. GORDON:
 2 Q. When you say --
 3 A. And in my 17 years of investigating
 4 outbreaks at the CDC, many of which were surgical
 5 site infection outbreaks, not a single one was
 6 associated with a Bovie, scalpel, drill.
 7 We're talking about the Bair Hugger. The
 8 Bair Hugger that's been shown to have bacterial
 9 contamination. The Bair Hugger that's been shown to
 10 release air that's contaminated. The Bair Hugger
 11 that's been shown to increase particle counts, and
 12 those particle counts correlate with CFUs. Some
 13 proportion of those particles are carrying bacteria.
 14 I know of no data that I have found -- if
 15 you can find one and show it to me, I'd be happy to
 16 look at it. But I've done extensive Medline
 17 searches looking at saws, looking at drills, looking
 18 at Bovies. And I can tell you there is not a single
 19 publication that I could find where any of those
 20 were associated with any prosthetic joint infection.
 21 Q. Okay. Did you find any studies where any
 22 of those things were associated with bacterial
 23 contamination?
 24 A. I don't know that I looked at them
 25 specifically for bacterial contamination. Do you

Page 106

1 mean intrinsic contamination, or do you mean
2 extrinsic contamination? Because most, if not all
3 of those devices, when they come into the operating
4 room are sterilized. Unlike the Bair Hugger, which
5 we know and 3M has acknowledged is contaminated, is
6 not sterile.

7 Q. Your understanding is that the drills and
8 the saws come into the operating room sterilized?
9 The whole saw, the whole drill, the whole
10 electrocautery unit?

11 A. The part that is having contact with the
12 patient? Yes.

13 Q. What about the rest of the equipment that
14 isn't having any contact with the patient?

15 A. Well, if it's not having contact with the
16 patient, then it may or may not be.

17 Most drills are sterilized. Ethylene
18 oxide sterilization.

19 Q. The whole drill?

20 A. The whole drill.

21 Q. The motor, the fan, every part of it?

22 A. In some cases, yes.

23 Q. In some cases, not yes?

24 MR. B. GORDON: Objection; form.

25 THE WITNESS: I'd have to look at

Page 107

1 different operating rooms. And, you know, obviously
2 we're talking about the United States. I'd say the
3 majority of them are. They're either sterilized or
4 they're covered.

5 BY MR. C. GORDON:

6 Q. And you've seen no studies that have
7 examined whether bacterial contamination of
8 electrocautery tips or drills or saws or anything
9 like that correlated with infections found in
10 implant patients?

11 A. I've not seen any such data.

12 MR. C. GORDON: Okay. And let me show you
13 Exhibit 10.

14 (Exhibit 10 marked.)

15 BY MR. C. GORDON:

16 Q. This is a paper called "Airborne bacterial
17 contamination during orthopedic surgery: A
18 randomized controlled pilot trial," by Oguz, et al.
19 2017.

20 Have you ever seen this before?

21 A. Yes.

22 Q. When?

23 A. I could not tell you when.

24 Q. It -- I don't see it on your list of --
25 either your list of references in your opinion or

Page 108

1 your list of "Additional Materials Reviewed." Did I
2 miss it?

3 A. I may have missed it.

4 Q. When did -- so is it something you would
5 have seen before you rendered your opinion in this
6 case?

7 A. As I said I don't remember.

8 Q. How did it come to your attention?

9 A. I don't remember if it came in from the
10 search. I don't remember.

11 Q. Do you remember reading a study that
12 actually -- that measured bacteria at the surgical
13 site comparing a Bair Hugger to a HotDog during
14 actual orthopedic surgeries?

15 A. I do remember this one. This was looking
16 at various short orthopedic procedures without an
17 implant. I think there was one, one knee
18 replacement. So it really is very different than
19 prosthetic joint infections with total hip and total
20 knee arthroscopy.

21 Q. So if the Bair Hugger is -- harbors all
22 this bacteria and spews out all these particles and
23 some portion of those particles -- you know, as
24 demonstrated by a handful of studies measuring
25 bubbles and smoke -- if it's doing all those things,

Page 109

1 you're saying it won't do that in a surgery
2 that's -- doesn't involve an implant?

3 MR. B. GORDON: Objection to form --

4 THE WITNESS: Well, I --

5 MR. B. GORDON: -- and theatrics.

6 (Reporter asks for repetition.)

7 MR. B. GORDON: Theatrics.

8 THE WITNESS: Well, I think the data
9 are -- are unanimously agreed upon in the scientific
10 community that the number of organisms needed to
11 cause an infection with an implant is much, much,
12 much less than that in a patient that does not have
13 an implant.

14 Furthermore, many of the studies -- in
15 contrast to Dr. Wenzel who doesn't believe duration
16 of operation has any impact or the number of people
17 in the operating room -- most studies show that in
18 fact those do correlate with infection. And the
19 longer the procedure, the more people in the room,
20 and the presence of an implant increases the risk of
21 infection.

22 MR. C. GORDON: Move to strike as
23 nonresponsive.

24 Q. My question, sir, is whether given all the
25 things that you say that the Bair Hugger does, is

Page 110

1 there any reason that it wouldn't increase CFUs when
2 used in some procedure other than an implant
3 procedure?

4 A. Well, as I said, it may increase the
5 particle counts and the CFUs in a non-implant
6 procedure. But given that the number of organisms
7 is so much lower, many studies show that you need 10
8 of the 3, 10 of the 5 organisms to cause an
9 infection if you don't have an implant. Whereas,
10 you can have as small as maybe even one organism.
11 Certainly 10 organisms can cause an infection with
12 an implant.

13 So you're talking about lot of difference
14 in risk associated with an implant in a patient
15 versus a non-implant. And these are all simple
16 procedures that are virtually all less than an hour;
17 surgery on a ligament and soft tissue. You know,
18 they're not even deep. We're talking about implants
19 where -- I thought we were going to be talking about
20 prosthetic joint infections. This has nothing to do
21 with prosthetic joint infection.

22 Q. Move to strike as nonresponsive.

23 Sir, does --

24 MR. B. GORDON: Objection. It's perfectly
25 responsive; you just didn't like the answer.

Page 111

1 BY MR. C. GORDON:

2 Q. Does this study demonstrate that when the
3 Bair Hugger is used as opposed to the HotDog, that
4 there are more bacteria entering the surgical
5 site -- field? Is that your understanding of it?

6 MR. B. GORDON: Take your time to read the
7 study and look at the data if you need to.

8 Object to the form of the question.

9 THE WITNESS: Well, actually, it says the
10 type of patient warming system had no significant
11 influence on bacterial counts.

12 BY MR. C. GORDON:

13 Q. So it's the exact opposite of what I just
14 said; right? This study using real patients showed
15 that when you use the Bair Hugger, it doesn't
16 increase bacteria in the surgical field over using
17 the HotDog?

18 MR. B. GORDON: Objection to the form.

19 BY MR. C. GORDON:

20 Q. Right?

21 MR. B. GORDON: Object to form.

22 THE WITNESS: Well, in using it in short,
23 non-implant surgical procedures --

24 MR. B. GORDON: I think you want to look
25 at -- is this the right paper? I want to make sure

Page 112

1 this is paginated correctly. I'm sorry. It's
2 paginated different from mine.

3 What was the question, Corey?

4 MR. C. GORDON: Have the court reporter
5 read it back.

6 MR. B. GORDON: Do you mind reading it
7 back? Just because he's -- let him finish reading
8 that, I guess.

9 Corey, is this your highlighting?

10 MR. C. GORDON: If it is, let's substitute
11 this out. Yeah, I believe it is.

12 THE WITNESS: What is the question?

13 (Record read as follows:

14 "Q. So it's the exact opposite of what
15 I just said; right? This study using
16 real patients showed that when you use
17 the Bair Hugger, it doesn't increase
18 bacteria in the surgical field over
19 using the HotDog?")

20 MR. B. GORDON: I object to the form and
21 that characterization of the outcome of the study.

22 THE WITNESS: Yeah, I guess in terms of
23 infection they -- the authors point out that the
24 surgery was minor; that there were no SSIs at all;
25 and that the end-- if you were really going to

Page 113

1 look at SSIs as your endpoint, you would need a much
2 larger study than this since infections are so rare.
3 And they point out that a large randomized
4 controlled study should be done, which was
5 recommended to 3M years and years ago and they
6 haven't done it.

7 MR. C. GORDON: Move to strike as
8 nonresponsive.

9 Q. Sir, it's a simple yes or no --

10 MR. B. GORDON: It was responsive.

11 BY MR. C. GORDON:

12 Q. Does this study show --

13 (Reporter asks for repetition.)

14 MR. B. GORDON: Objection; it was
15 responsive.

16 BY MR. C. GORDON:

17 Q. Does this study show that when the Bair
18 Hugger is compared in a randomized trial head to
19 head with a HotDog there is no difference in the
20 number of bacteria that make it to the surgical site
21 whether you're using the Bair Hugger or the HotDog?

22 MR. B. GORDON: Objection to counsel's
23 characterization. It's argumentative. It's asked
24 and answered. He can answer the question the way he
25 sees fit.

Page 114

1 THE WITNESS: Well, what they say is,
2 again, that the study is very limited. That they
3 had no difference in growth. But their
4 multi-variant analysis -- which is very limited
5 since there are only 80 patients in this study and
6 no surgical site infections -- that indicate that a
7 longer duration of surgery increased bacterial count
8 on plates 1 and 4 and the absence of laminar flow
9 increased bacterial counts on plates 1 and 6
10 significantly. And that there was a trend that
11 longer duration increased the bacterial counts.

12 BY MR. C. GORDON:

13 Q. Right. But no difference between the --

14 A. But there again it was very limited
15 because there's only 40 patients in each group and
16 there were no infections.

17 Q. Only 40 patients. And --

18 A. In each group.

19 Q. Right. So a total of 80 patients?

20 A. Correct. So if there was a 1 percent
21 infection risk, you'd have .8.

22 Q. Great. I'm not asking about infections.
23 I'm asking about bacteria. That study showed no
24 difference in bacteria; right?

25 MR. B. GORDON: Objection to form. You're

Page 115

1 mischaracterizing the evidence. You're totally
2 ignoring Table 2. Just --

3 MR. C. GORDON: Object to the form of the
4 -- "object to the form."

5 Move to strike counsel's speaking
6 objection. Stop it, Ben.

7 MR. B. GORDON: I missed -- I object --

8 MR. C. GORDON: Stop it, Ben.

9 MR. B. GORDON: -- you're
10 mischaracterizing what he said.

11 (Reporter interruption.)

12 BY MR. C. GORDON:

13 Q. Obviously, Dr. Jarvis, Mr. Gordon wants
14 you to look at Table 2.

15 MR. B. GORDON: You want to cherry-pick
16 what you want him to --

17 MR. C. GORDON: No. Stop that.

18 MR. B. GORDON: -- answer.

19 (Reporter interruption.)

20 MR. C. GORDON: Stop your speaking
21 objections.

22 MR. B. GORDON: I'm going to object --

23 MR. C. GORDON: That one -- that one, I'm
24 sorry, is over the top. And if you're going to pull
25 stuff like that, we're going to terminate and go to

Page 116

1 the court.

2 MR. B. GORDON: Corey, I'm trying to wait
3 until you finish so -- in respect for the court
4 reporter so she can take us both down.

5 If you're mischaracterizing the evidence,
6 I'm going to object to it. The doctor can look at
7 the report and answer the question the way he sees
8 fit. But if you're characterizing it in a way
9 that's unfair and unrepresentative of what's in the
10 study, then I'm going to object to that.

11 MR. C. GORDON: You're more than welcome
12 to object, but --

13 MR. B. GORDON: If you want to call the
14 judge, you call her right now.

15 MR. C. GORDON: You're more than welcome
16 to object. But saying "Figure 2" is of the most
17 clear and egregious form of a speaking objection.

18 MR. B. GORDON: Because you continually
19 ask a question that ignores that part of it because
20 you want to cherry-pick just the part you like.

21 MR. C. GORDON: Then object that it
22 mischaracterizes the evidence.

23 MR. B. GORDON: I object you're
24 mischaracterizing Table 2. Because it's right
25 there.

Page 117

1 MR. C. GORDON: I didn't characterize
2 Table 2.

3 MR. B. GORDON: You characterized the
4 evidence as --

5 MR. C. GORDON: I'm --

6 MR. B. GORDON: -- not being where it is
7 and what it is.

8 MR. C. GORDON: I'm through arguing with
9 you.

10 Q. You know what? Let's move on, Doctor.
11 You -- I think you made it pretty clear what you
12 think about the Oguz paper. And even though you saw
13 the Oguz paper, you didn't list it as either one of
14 your references or either even the additional
15 materials you reviewed; right?

16 A. I must have missed it.

17 Q. "Must have missed it." Okay.

18 On a number of occasions you talk about
19 Dr. Wenzel, your disagreements with Dr. Wenzel.
20 You've had some disagreements with Dr. Wenzel going
21 back many years; haven't you?

22 A. Well, we probably disagree on some things,
23 yes.

24 Q. Well, you had a rather vigorous public
25 disagreement a few years ago with Dr. Wenzel on

Page 118

1 the -- MRSA screening; right?

2 MR. B. GORDON: Objection; argumentative.
3 Calls for facts not in evidence.

4 (Exhibit 9 marked.)

5 BY MR. C. GORDON:

6 Q. I'm showing you Exhibit 9. It's a --

7 MR. B. GORDON: 9?

8 MR. C. GORDON: Yeah. I had skipped it
9 earlier.

10 Q. Series of letters back and forth to the
11 editor of JAMA. Your -- your letter appears, I
12 think, on the second page. Does that jog your
13 memory as to -- I can mark more if you want.

14 MR. B. GORDON: What?

15 THE WITNESS: I'm trying to figure out
16 what this has to do with Dr. Wenzel. This was
17 actually a letter to the Ed. for about a Harbarth
18 paper from Switzerland. I don't see Dr. Wenzel's
19 name anywhere here.

20 BY MR. C. GORDON:

21 Q. Well, I'm not going to take the time to
22 find it.

23 You don't recall having any back and forth
24 where you disagreed with Dr. Wenzel about MRSA
25 screening and is- -- isolation and detection --

Page 119

1 detection and isolation of --

2 A. Active --

3 Q. -- MRSA patients?

4 A. -- detection and isolation?

5 (Reporter asks for repetition.)

6 Q. Active detection and isolation?

7 A. Yes.

8 Q. And you and Dr. Wenzel had different
9 viewpoints; right?

10 A. Well, we used to have the same viewpoint
11 and then he changed his viewpoint.

12 Q. Okay. And what was his -- what was the
13 viewpoint that you shared at one point?

14 A. When he was at University of Virginia, he
15 was one of the first in infection control to begin
16 an active program of active detection and isolation
17 of MRSA patients. He showed at University of
18 Virginia a significant reduction in MRSA infections
19 with that approach. Then about a decade later, he
20 decided we shouldn't do that. And --

21 Q. Which part of that?

22 MR. B. GORDON: He's not finished.

23 THE WITNESS: And he has come up with this
24 idea of horizontal versus vertical infection
25 control. And I don't know if we want to go too much

Page 120

1 time into that. But basically he would say vertical
2 infection control would be like organism-specific.
3 Like doing something for MRSA that might not have
4 anything to do with C. difficile.

5 (Reporter asks for repetition.)

6 THE WITNESS: C. diff- -- Clostridium
7 difficile. C-L-O-S-T-R-I-D-I-U-M.
8 D-I-F-F-I-C-I-L-E.

9 MR. B. GORDON: Just C. difficile.
10 Capital C. difficile.

11 THE WITNESS: That instead of doing that,
12 he should do just horizontal things, like hand
13 hygiene. A group of interventions that would
14 prevent catheter-related bloodstream infection. But
15 no longer identified colonized MRSA patients even
16 though he knows and he has shown that colonized MRSA
17 patients contaminate the environment and lead to
18 transmission of MRSA just as well as infected
19 patients.

20 So he changed his point of view despite
21 the fact that he had previously published one of the
22 first studies showing the efficacy of that approach.

23 BY MR. C. GORDON:

24 Q. You have consistently been an advocate for
25 MRSA screening of all hospital patients; right?

Page 121

1 A. No. I have been in favor of patient
2 safety and reducing infections in all settings.

3 And with MRSA I have recommended that
4 hospitals do a risk assessment to identify who their
5 high-risk patients are and then do targeted
6 surveillance of those high-risk patients to identify
7 colonized and infected patients and place them in
8 isolation. Because there are literally hundreds of
9 published studies showing that that approach
10 significantly reduces MRSA infections. Now, some
11 hospitals have decided that it's just more feasible,
12 practical for nursing personnel to screen everyone.
13 Rather than just targeted patients.

14 But if you look at data, for instance,
15 from the VA system, where they screen everyone, they
16 have had a dramatic decrease in MRSA infections. If
17 you look at some other hospital systems, the same
18 thing has been shown. So to turn around now and say
19 this approach does not work makes no sense.

20 Q. When you talk about MRSA screening how is
21 the screening done?

22 A. Screening is done by doing swabs usually
23 of the nose. You can do other body sites. But of
24 the nose. And then there's a variety of approaches
25 afterwards. You can either use culture; you could

<p style="text-align: right;">Page 122</p> <p>1 use polymerase chain reaction; you could use 2 selective media, not selective media. 3 (Reporter asks for repetition.) 4 MR. B. GORDON: Polymerase chain reaction, 5 PCR. 6 THE WITNESS: PCR. 7 So you could use routine culture. You 8 could use polymerase chain reaction or PCR. You 9 could use selective or nonselective media. 10 So depending upon balancing how many are 11 testing and how fast you want the result, cost 12 issues, you can use one of those approaches. 13 BY MR. C. GORDON: 14 Q. You have been a consultant to one or more 15 companies that manufacture products that are used 16 for the -- for that detection; right? 17 A. I consult for companies that do and 18 companies that don't. 19 Q. But you -- my question specifically 20 relates to companies that do. Have you -- you have 21 consulted for companies that have a financial 22 interest in increased MRSA surveillance; right? 23 A. Well, I've consulted for companies that 24 have made either polymerase chain reaction testing 25 or types of culture media that could be used for</p>	<p style="text-align: right;">Page 123</p> <p>1 such testing. 2 Q. One of those is right near here; isn't it? 3 Becton Dixon -- Dickinson? 4 A. I don't know if they're here, but BD is 5 one of those companies. I haven't spoken in terms 6 of MRSA for BD in probably five years. 7 Q. When you have written things about MRSA 8 screening, you think it's -- you disclose your -- 9 the fact that you've been a consultant to, among 10 others, BD; right? 11 MR. B. GORDON: Objection to form. 12 Argumentative. 13 THE WITNESS: It depends on what I'm 14 writing, where I'm writing, what I'm saying. I 15 have -- I would be hard-pressed to say that I've 16 ever written an article where I've recommended a 17 specific product. I talk generically about 18 screening. How you screen is up to you to decide. 19 (Exhibit 11 marked.) 20 BY MR. C. GORDON: 21 Q. Show you what's been marked as Exhibit 11. 22 This study you co-authored; correct? 23 A. Correct. 24 Q. And in this case you were comparing a 25 couple of modalities for central line-associated</p>
<p style="text-align: right;">Page 124</p> <p>1 bloodstream intravenous connectors or something. I 2 don't -- how do you explain what the device is you 3 were -- 4 A. This was looking at the incidence of 5 central line-associated bloodstream infections 6 associated with two different types or multiple 7 types of needleless connectors. 8 Q. Needleless -- needleless connector. 9 That's -- is that the device? Is that how you 10 describe it? 11 A. Correct. 12 Q. Okay. And you were comparing one type of 13 needleless connector to another; right? 14 A. Correct. 15 Q. And your study concluded that one type was 16 better than the other; right? 17 A. Well, it actually wasn't a one-on-one. It 18 was comparing one to a variety of others. 19 Q. The one that you were comparing to a 20 variety of others was the zero fluid displacement 21 needleless connector; right? 22 A. Correct. 23 Q. And that was made by RyMed Technologies; 24 right? 25 A. Correct.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. Did you have any consulting arrangement 2 with RyMed Technologies? 3 A. I did not. 4 Q. Let me show you what's been marked 5 Exhibit 12. 6 Oh, by the way. Exhibit 11. This is 7 published in a peer-reviewed journal; right? 8 A. It was, yes. 9 Q. So it went through the whole peer-reviewed 10 process; right? 11 A. Correct. 12 Q. And that's important to you; isn't it? 13 Peer-review? 14 A. Absolutely. 15 Q. And you -- earlier this morning you used 16 that phrase several times. If a study is 17 peer-reviewed, in your mind that -- that's some 18 assurance that it's reliable; right? 19 MR. B. GORDON: Object to form. Object 20 as -- 21 THE WITNESS: No, I don't know. You know, 22 I was an editor for a journal for -- that actually 23 Dr. Wenzel initiated -- for over two years. I don't 24 know what the review process is. I think the value 25 of peer-reviewed is it's other scientists looking at</p>

Page 126

1 the data and making hopefully an objective
2 evaluation of the merits of that paper.

3 BY MR. C. GORDON:

4 Q. You would agree with me that
5 peer-reviewers can only review what they're
6 presented with; right?

7 A. Absolutely.

8 Q. So if an author or authors mischaracterize
9 the data or withhold certain data, peer-reviewers
10 can't determine that based on what's presented;
11 right?

12 MR. B. GORDON: Object to the form.
13 Assumes facts not in evidence.

14 THE WITNESS: I guess that's somewhat
15 true. Obviously if it's revealed, then they can.
16 If it's not revealed, they can't.

17 MR. C. GORDON: Okay. So I'm going to
18 show you Exhibit -- what's that? 12?

19 (Exhibit 12 marked.)

20 BY MR. C. GORDON:

21 Q. Have you seen Exhibit 12 before?

22 A. I know about it. I don't know that I've
23 seen this specific piece of paper before.

24 Q. Okay. Well, you know that the article you
25 co-authored that we marked as Exhibit 11 was

Page 127

1 actually retracted by the journal; correct?

2 A. Correct.

3 Q. And originally it was retracted because
4 there was a failure to disclose a conflict of
5 interest; right?

6 A. By Dr. Chernecky.

7 Q. But once they -- the review committee at
8 Georgia Regents University dug into it, they found
9 not only that there was this failure to disclose
10 this conflict of interest, but there were questions
11 raised about the methods and data presented in the
12 article; in particular, the consistency of the
13 statistics over various study periods as well as the
14 methods by which study sites were chosen. Right?

15 A. That's what it says, yes.

16 Q. And they concluded after this
17 investigation, that the science was flawed; right?

18 A. Correct.

19 (Exhibit 13 marked.)

20 BY MR. C. GORDON:

21 Q. So now if one wants to look at the journal
22 of this article which you co-authored, what they see
23 is Exhibit 13; right?

24 A. I haven't pulled it up, but I would guess
25 yes.

Page 128

1 Q. Do you have any other articles you
2 co-authored been retracted?

3 A. Not to my knowledge. And I was unaware of
4 Dr. Chernecky's conflict of interest as well.

5 Q. Were you aware of the flawed science?

6 A. I don't know that --

7 MR. B. GORDON: Objection; argumentative.

8 THE WITNESS: Well, first of all, I don't
9 know that I would agree with that. ICU Medical is
10 the one that brought this up. And they've sued
11 virtually every needleless connector manufacturer
12 that I know of. And they didn't like the data. I
13 don't know that I would agree with Georgia Regents.
14 I think their concern was more the maintenance of
15 the records than anything else. And the potential
16 conflict of interest that Dr. Chernecky may have
17 had. I looked at the data and I don't think it was
18 flawed.

19 BY MR. C. GORDON:

20 Q. So you looked at the data and didn't think
21 it was flawed. And that was -- the way it was
22 presented to the peer reviewers, they apparently
23 didn't think it was flawed because they signed off
24 on it; right?

25 A. Correct.

Page 129

1 Q. And after conflict of interest was raised,
2 an interdisciplinary scientific review committee
3 convened by senior leadership at Georgia Regents
4 University, looked at it. And they concluded that
5 there were questions about the methods and data and
6 the consistency of the statistics. And they
7 concluded -- this independent scientific review
8 committee concluded that the science was flawed;
9 right?

10 MR. B. GORDON: Objection; asked and
11 answered.

12 THE WITNESS: Well, you read that before.
13 Correct.

14 BY MR. C. GORDON:

15 Q. And you disagree with that?

16 MR. B. GORDON: Asked and answered.

17 THE WITNESS: Well, I didn't see their
18 review. They obviously didn't share their review
19 with me. I have no idea if the people at -- my
20 guess is the people that did the review at Georgia
21 Regents University know nothing about needleless
22 connectors, know nothing about the science of this.
23 I have no idea what the discussions were between
24 Dr. Chernecky and that committee. So I can't really
25 comment other than they made their review and made

Page 130

1 their decision.

2 BY MR. C. GORDON:

3 Q. Did it concern you that a paper you -- you
4 had your name on has -- is now retracted because an
5 independent review committee concluded it was flawed
6 science?

7 A. I wasn't happy about it, no.

8 Q. Well, did you do anything to find out what
9 it was they thought was flawed about it?

10 A. No. What do you think, Georgia Regents
11 University is going to change their action because I
12 give them a call and ask them what's going on? That
13 was really an evaluation of Dr. Chernecky, not me.
14 So it was between she and her university.

15 Q. The investigation of the conflicts of
16 interest involved Dr. Chernecky; right?

17 A. Correct.

18 Q. But the investigation of the statistics
19 and the data analysis, stuff that they did after
20 they started looking into conflicts of interest,
21 that involved you too; right?

22 MR. B. GORDON: Objection; asked and
23 answered.

24 THE WITNESS: Well, I've seen the data and
25 I've done the statistics on the data and I don't

Page 131

1 know what they found that they had problems with.

2 BY MR. C. GORDON:

3 Q. But you didn't try to find out?

4 A. No.

5 Q. You weren't curious?

6 A. As I say, I saw the data and did the
7 analysis. So I -- I think I know how to do a T
8 test, Fisher's Exact test, or chi-squared test.

9 (Reporter asks for repetition.)

10 T test, Fisher's Exact test. They're not
11 very complicated. So I don't really think it was a
12 statistical analysis that they were concerned about.

13 Q. But you never bothered to find out what
14 they were concerned with?

15 A. I don't think they would have told me.
16 But I didn't call them, if that's the question.

17 Q. All right. Well, did you call
18 Dr. Chernecky ask her why this was retracted?

19 A. I can't remember if I had a conversation
20 with her or not.

21 MR. C. GORDON: Why don't we take a lunch
22 break.

23 MR. ASSAAD: Before we go on a break, I'd
24 just like counsel for 3M to identify himself on the
25 record so we have it on the transcript.

Page 132

1 MR. BOONE: Sure.

2 I'm Mordecai Boone. M-O-R-D-E- --

3 (Reporter asks for repetition.)

4 M-O-R-D-E-C-A-I. Last name is Boone,
5 B-O-O-N-E. And I'm seconded counsel at 3M Company.

6 THE VIDEOGRAPHER: The time is 12:06 p.m.
7 We're off the record.

8 (Recess taken from 12:06 p.m. to 12:53 p.m.)

9 THE VIDEOGRAPHER: This marks the
10 beginning of Volume I, file 3 in the deposition of
11 Dr. William Jarvis. The time is 12:53 p.m. And we
12 are on the record.

13 (Exhibit 14 marked.)

14 MR. C. GORDON: Dr. Jarvis, let me show
15 you what I've marked as Exhibit 14.

16 Q. This is a document that your counsel
17 handed me this morning. It looks like it's a
18 printout of an e-mail?

19 A. Correct.

20 Q. Sent from you to Dr. Darouiche a couple of
21 weeks ago, like three weeks ago?

22 A. Yeah, that's about right. Yup.

23 Q. Did you get a response?

24 A. No.

25 Q. You say in this e-mail to Dr. Derouiche,

Page 133

1 "The other side's experts have been attacking and
2 criticizing your paper."

3 Did I read that correctly?

4 A. Mm-hmm.

5 Q. Which experts have attacked and criticized
6 Dr. Darouiche's paper?

7 A. I can't list them specifically. But I was
8 told that.

9 Q. You were told it?

10 A. Mm-hmm.

11 Q. You didn't read it yourself?

12 A. No.

13 Q. Okay. Do you know -- well, were you told
14 any of the defense experts were attacking or
15 criticizing Darouiche paper?

16 MR. B. GORDON: I may have missed a
17 question but I'm going to object to the extent it
18 calls for information discussed between counsel.
19 And, Dr. Jarvis, I caution you not to answer.

20 MR. C. GORDON: Yeah. If you're claiming
21 there's some sort of privilege, he waived it when he
22 told Dr. Darouiche that the other side's experts
23 have been attacking and criticizing your paper.

24 MR. B. GORDON: You can take that
25 position, but I'm not sure that would be -- I'm not

Page 134

1 sure where he got the information. But if it came
2 from me, I'm telling him not to answer and you can
3 file a motion.

4 BY MR. C. GORDON:

5 Q. I want to know what your basis was for
6 telling Dr. Darouiche that the other side's experts
7 have been attacking and criticizing your paper.

8 MR. B. GORDON: And if your basis was from
9 review of data, materials, analysis, then go ahead.
10 If it's from me and I don't know if it is, but if it
11 is, don't answer it.

12 THE WITNESS: No.

13 BY MR. C. GORDON:

14 Q. No what?

15 A. It's not from reading something.

16 Q. So is this -- this is based on something
17 Mr. Ben Gordon told you; is that what your testimony
18 is?

19 MR. ASSAAD: I instruct you not to answer
20 anything other than that question. No substance of
21 anything we talked about.

22 THE WITNESS: Yes.

23 BY MR. C. GORDON:

24 Q. Okay. What did Mr. Ben Gordon tell you
25 was -- constituted attacking and criticizing

Page 135

1 Dr. Darouiche's paper from the defense experts that
2 you told -- that you sent this e-mail to
3 Dr. Darouiche about?

4 MR. ASSAAD: Again, I'm going to object as
5 that -- any conversation we had with Dr. Jarvis
6 being protected by the attorney work product
7 privilege. Instruct you not to answer.

8 BY MR. C. GORDON:

9 Q. You're going to follow his instruction, I
10 assume?

11 A. Yes.

12 Q. Do you have any activities in connection
13 with the CDC currently? Are you on any panels or
14 advisory committees or anything like that?

15 A. No.

16 Q. National Institutes of Health? Are you on
17 any committees there?

18 A. No.

19 Q. WHO?

20 A. I work with people with WHO but nothing
21 formal.

22 Q. FDA?

23 A. Yes.

24 Q. What do you do for the FDA?

25 A. I'm chairman on one of their committees.

Page 136

1 Q. What's -- which committee?

2 A. It's got a long name. "The General
3 Hospital and Personal Use Panel."

4 Q. What is that panel?

5 A. It's an FDA committee that primarily
6 focuses on medical devices, occasionally on
7 methodologies, that FDA would use for assessing
8 medical devices.

9 Q. All medical devices or is it some subset
10 of medical devices?

11 A. I don't know that I can answer that.
12 I'm -- we've discussed a number of different types
13 of medical devices. Whether they have
14 responsibility for all of them or some subset, I'm
15 not sure.

16 Q. How long did you chair that committee?
17 (Reporter asks for repetition.)

18 How long have you been chair? I'm sorry.
19 Was that -- if it's in your resume, I don't --

20 A. Yeah, it's in my resume.

21 Q. I'm sorry.

22 A. It's been years.

23 Q. Okay. That's fine. I just didn't -- if
24 it's in your resume and it's been years, that's all
25 I want to know.

Page 137

1 A. Since 2007.

2 Q. Does that -- help me out here. What is
3 the jurisdiction of the committee? Is it to review,
4 you know, new device applications or 510(k)s or --
5 I'm just -- what -- what does the committee do?

6 A. Well, we're somewhat like a -- the HICPAC
7 for CDC. Healthcare Infection Control Practices
8 Advisory Committee. We're basically an advisory
9 committee. So if the FDA has specific issues they
10 want to address, they call me, e-mail me, arrange
11 for a meeting, provide materials that the committee
12 members look at. There may be formal presentations.
13 We do not review 510(k) applications.

14 An example of it was that we've looked at,
15 for instance, infusion pumps for insulin. Looked at
16 methodologies for detecting Jakob Creutzfeldt agent.
17 So it spans a wide variety of different activities
18 but it's really directed by FDA.

19 Q. Does it meet regularly?

20 A. I would say it meets irregularly.

21 Q. Is it a committee that is called -- called
22 upon when the FDA needs it as opposed to having
23 regularly scheduled --

24 A. Exactly, yes.

25 Q. When was the last time you had a meeting?

Page 138

1 A. Probably a year and a half ago.
 2 Q. So it's not a frequent thing for you?
 3 A. Correct.
 4 Q. Has any -- have you addressed any issues
 5 relating to Bair Hugger in connection with that
 6 committee?
 7 A. No.
 8 Q. Have you raised anything in connection
 9 with the Bair Hugger through that committee?
 10 A. No.
 11 Q. Have you communicated with anybody at the
 12 FDA about what you've -- the opinions you've
 13 expressed in -- in your expert opinion here about
 14 the Bair Hugger?
 15 A. Well, as you know I've signed a
 16 confidentiality agreement. So I would love for it
 17 to be raised -- released if you would like to do
 18 that. I'd be more than happy to. I've been --
 19 tried to be very careful with who I've communicated
 20 with and what I've communicated about Bair Hugger
 21 until I'm allowed to.
 22 Q. So I take it that you're saying no, you
 23 haven't communicated with anybody at the FDA?
 24 MR. B. GORDON: Objection; asked and
 25 answered.

Page 140

1 I'm not sure.
 2 Q. So you don't know whether it was something
 3 you found on your own or somebody provided it to
 4 you? You don't know?
 5 A. It may have been both. I don't remember.
 6 Q. And how long ago do you recall first
 7 seeing it?
 8 A. I think pretty shortly after it came out.
 9 I'm doing Medline searches all the time.
 10 Q. Do you know when it came out?
 11 A. I'm thinking it was January. But it
 12 doesn't say, so I don't remember.
 13 Q. So you -- your recollection is that it was
 14 a while ago as opposed to in the last two, three,
 15 four or five weeks?
 16 A. Yeah, I don't think it was -- as I say, it
 17 doesn't have a date on here --
 18 Q. Okay. Your --
 19 A. -- or a month anyway.
 20 Q. Your expert report was January -- excuse
 21 me. Strike that. Your expert report was March 31,
 22 2017. Do you know whether you had seen Exhibit 15
 23 before or after that date?
 24 A. I think it was probably after.
 25 Q. Probably after?

Page 139

1 THE WITNESS: Correct.
 2 BY MR. C. GORDON:
 3 Q. How about the CDC; same thing?
 4 A. Same thing.
 5 Q. Any government regulatory agency? Have
 6 you communicated with anybody in connection with --
 7 with any government body concerning your -- your --
 8 the issues you raise with respect to the Bair
 9 Hugger?
 10 A. No. Until the confidentiality agreement
 11 is lifted, I'm somewhat prohibited from doing so.
 12 Q. One of the items on your "Additional
 13 Materials Reviewed," Exhibit 3, was -- or is --
 14 Augustine 2017; is that right?
 15 A. Correct.
 16 (Exhibit 15 marked.)
 17 BY MR. C. GORDON:
 18 Q. Let me show you what I've marked as
 19 Exhibit 15 and ask you if that is the Augustine 2017
 20 document you're referring to in your "Additional
 21 Materials Reviewed," Exhibit 3.
 22 A. Yes.
 23 Q. How did you first become aware of Exhibit
 24 15?
 25 A. I'm not sure if it came up in a search.

Page 141

1 A. I can't be absolutely sure but I think it
 2 was probably after.
 3 Q. After March 31?
 4 A. Yeah.
 5 Q. But not in the last month? Not as recent
 6 as that?
 7 A. Correct.
 8 Q. Okay. And is there anything in Exhibit 15
 9 that impacts your opinions at all?
 10 A. Well, I think it's like the material I
 11 quoted in my report. You know, this is -- to me
 12 it's kind of putting pieces of a puzzle together and
 13 it's an additional piece of information that -- that
 14 supports the dangers of the Bair Hugger.
 15 Q. So this is something you would consider a
 16 reference material that you would rely on to support
 17 your opinion?
 18 A. I --
 19 MR. B. GORDON: Object to the form.
 20 Characterization of reliance.
 21 THE WITNESS: I think it's -- as I say,
 22 it's a piece of the puzzle like all the other
 23 references that I have in my report.
 24 BY MR. C. GORDON:
 25 Q. Okay. Well, if -- this isn't a reference

Page 142

1 in your report so that's what I'm trying to
2 understand. I mean, we went -- we talked about the
3 Cristina study. That's also on your "Additional
4 Materials Reviewed." But that's -- you know, you
5 rejected that study as something you need to
6 consider; right?

7 MR. B. GORDON: Object to the form.
8 Mischaracterizes his testimony.

9 THE WITNESS: Right. I didn't say I
10 rejected it. I read it and there were concerns I
11 had in that particular study.

12 BY MR. C. GORDON:

13 Q. Did you have any concerns about
14 Augustine's study, Exhibit 15?

15 A. Well, from reading it, it seemed like it
16 was kind of following some of the same methodology
17 as the Albrecht study. So, you know, seemed pretty
18 straightforward.

19 Q. So unlike Cristina, you didn't have any
20 concerns with Exhibit 15; is that right?

21 MR. B. GORDON: Object to the form.
22 Argumentative.

23 THE WITNESS: Well, as I say, it provided
24 data from three hospitals. Those hospitals
25 collected the data. It seemed like Dr. Augustine

Page 143

1 was pretty much as concatenating the information and
2 had somebody that he paid, it sounds like, to do the
3 statistics on it. So he was basically just kind of
4 coordinating it.

5 BY MR. C. GORDON:

6 Q. Do you -- did you read Dr. Augustine's
7 deposition?

8 A. I don't believe so.

9 Q. How did you -- how were the depositions
10 you did read selected?

11 A. You would have to ask counsel that
12 question.

13 Q. So you didn't ask for any specific
14 witnesses?

15 A. Correct.

16 Q. And I think in your December billing
17 statement you listed the -- several depositions that
18 you had read. Hansen, Maharaj, Reed, Hannenberg,
19 Albrecht, Bergstrom, Hamer, and Sessler.

20 A. Correct.

21 Q. And then on your "Additional Materials
22 Reviewed," Exhibit 3, there's some additional
23 depositions listed. So would those have been
24 depositions that you read after your expert report?
25 There's some overlap, I know that.

Page 144

1 A. Yeah, some would be, some wouldn't be. As
2 you say, there's some overlap. There's Albrecht,
3 Reed, Bergstrom, Hamer, Sessler, Kurtz are all --
4 Hansen, Maharaj -- are all there. I think Lampotang
5 was long time ago.

6 Q. Okay. McGovern?

7 A. McGovern also is --

8 Q. Go ahead.

9 A. I think the McGovern was probably done
10 December-ish of last year.

11 Q. Yeah. It was actually early January of
12 this year.

13 A. So definitely Stonington was after.

14 Q. It would have been --

15 A. Koenigshofer would be after.

16 (Reporter asks for repetition.)

17 Koenigshofer would be after.

18 Q. McGovern was originally scheduled for
19 December but I got campylobacter.

20 (Reporter asks for repetition.)

21 MR. C. GORDON: Campylobacter.

22 MR. ASSAAD: Got sick. Bacteria. Got to
23 wash those hands.

24 MR. C. GORDON: People that prepared my
25 food needed to wash their hands.

Page 145

1 MR. B. GORDON: British food. Sorry.

2 BY MR. C. GORDON:

3 Q. So you read McGovern before you wrote your
4 report; is that your recollection?

5 A. I can't say for sure on that. I certainly
6 read the paper. I can't say about the deposition.

7 Q. And when you -- well, okay. When you read
8 the deposition -- when you refer to depositions, did
9 you also get the exhibits that were part of the
10 depositions or did you just get the transcript?

11 A. On that specific one I don't remember.

12 Q. On any of them.

13 A. I think on some I got exhibits; others I
14 didn't.

15 Q. I don't see Legg on any of these lists.
16 So you didn't read Dr. Legg's deposition?

17 A. I don't believe so.

18 Q. And it lists Albrecht. There's actually
19 two volumes of Albrecht. Do you know if you read
20 both of them?

21 A. I believe I've read one of the two.

22 Q. But not the second one?

23 A. No. I think I read the second one and not
24 the first. I think.

25 Q. So I'm still trying to understand what

Page 146

1 relevance Exhibit 15, the Augustine study, has to
2 your opinions. It's now on your "Additional
3 Materials Reviewed" list, but I don't know if that
4 means using something that you consider a reliable
5 piece of medical literature that you're going to
6 base your opinions on or it's --

7 A. Well, I think it's --

8 MR. B. GORDON: Whoa, whoa, whoa, let him
9 finish. Because I want to object.

10 Are you done, Corey?

11 BY MR. C. GORDON:

12 Q. Or --

13 Yeah.

14 Or it's something you're not taking into
15 consideration.

16 MR. B. GORDON: Object to the form,
17 counsel's characterization.

18 Go ahead.

19 THE WITNESS: Well, obviously since it's
20 on my list everything on my list I take into
21 consideration. I think that it is an additional
22 piece of the puzzle, every one of these studies is
23 further dated to support my belief that the Bair
24 Hugger is a device that withdraws air that's not
25 sterile, it's contaminated coming out of the device,

Page 147

1 it increases particle counts over the operative
2 field. And I think is causative for surgical site
3 infections, particularly with patients with
4 prosthetic joint infections.

5 And I think this is another piece of
6 information or data from a peer-reviewed journal
7 that supports that belief. And the three different
8 hospitals using what looks like pretty similar
9 methodologies found an increase in prosthetic joint
10 infections when they were using the Bair Hugger.

11 BY MR. C. GORDON:

12 Q. So you believe that supports your opinion;
13 right?

14 A. Correct.

15 Q. And you're relying on the scientific
16 integrity of this Exhibit 15; right?

17 MR. B. GORDON: Object to the form. And
18 the use of the word "relying."

19 THE WITNESS: Yeah, I don't know that I'm
20 relying on it. It's a peer-reviewed journal that at
21 least from looking at the data submission and the
22 date of acceptance and publication and looking
23 actually at the journal's website, that it's like
24 any other peer-reviewed journal. So it's gone out
25 for peer review.

Page 148

1 BY MR. C. GORDON:

2 Q. Why did you look at the website?

3 A. Because I'm not familiar with that
4 specific journal. I don't tend to read orthopedic
5 papers. I had not heard of it before so I looked at
6 it to see what it was all about.

7 Q. So did you see the fee that they charge
8 for publishing papers?

9 A. I did see -- well, it's not as you
10 describe. You don't pay them and then they publish
11 your paper as they point out in the -- on the site,
12 they don't require any money when you submit the
13 paper. It's only when it's accepted for
14 publication. And that's no different than the
15 journal that Dr. Wenzel's an editor on. New England
16 Journal charges page charges. Lancet charges page
17 charges --

18 THE REPORTER: I'm sorry. "And that's
19 something the"?

20 THE WITNESS: New England Journal of
21 Medicine charges page charges. Lancet charges page
22 charges. Every -- American Society for Microbiology
23 Journal charges page charges. So that's a very
24 common practice. And particularly journals that
25 have online availability to virtually everyone.

Page 149

1 They -- virtually all charge page charges. So I
2 don't think that's anything unusual.

3 BY MR. C. GORDON:

4 Q. Does New England Journal require authors
5 to identify two peer reviewers?

6 A. Actually, I've had quite a few articles
7 published in the New England Journal and submitted
8 in the New England Journal. And on every single one
9 I've submitted we've given recommendations for
10 reviewers. And I can tell you having been an editor
11 of the journal, that is very helpful. Otherwise
12 you're going into your database and just picking
13 somebody at random. And I might pick you to do a
14 review of a paper on which you know nothing. So
15 it's actually much more useful if the authors can
16 provide the names -- and preferably more than two --
17 of people who have expertise in the area.

18 Q. Move to strike as nonresponsive. Let me
19 emphasize my -- the part of my question that I --
20 I -- you may not have heard.

21 Does the New England Journal require
22 authors to submit two peer-re- -- names of two peer
23 reviewers?

24 MR. B. GORDON: Objection to form. Asked
25 and answered.

Page 150

1 THE WITNESS: Well, I think the answer to
2 that I'm not aware of any journal that requires you
3 to do that. But most journals are more than happy
4 when you do do that.

5 BY MR. C. GORDON:

6 Q. Do you know Dr. Augustine?

7 A. Never met him.

8 Q. Have you ever talked to him?

9 A. Nope.

10 Q. Do you know that he's quoting your expert
11 report in marketing materials?

12 A. No, I was not aware of that, no.

13 Q. Does that surprise you?

14 MR. B. GORDON: Objection; argumentative.

15 THE WITNESS: I'd have to see it. I don't
16 know, you know, what he's saying.

17 BY MR. C. GORDON:

18 Q. Let's look at Exhibit 1, your expert
19 report. And I'm going to ask some questions. Let's
20 start on page 5. At the top of the page where you
21 say -- where you emphasize that "None of these
22 patient-specific characteristics causes the
23 infection; the pathogen causes the infection." Do
24 you see that?

25 A. Yes.

Page 152

1 in your prosthetic device you have an increased risk
2 of going on and developing an infection.

3 Q. Would you characterize that as a host
4 immunity factor?

5 A. Absolutely it would be, sure.

6 Q. And would you agree that there are
7 patient-specific risk factors that actually increase
8 the bio-burden of bacteria that the patient brings
9 to the table?

10 MR. B. GORDON: Object to the form.

11 THE WITNESS: You mean specifically on
12 certain body sites or more likely have
13 naso-colonization? Can you ask it a little bit --

14 BY MR. C. GORDON:

15 Q. Well, let's back it up a different way.
16 On the next paragraph you say, "exogenous sources
17 account for the SSIs"; right?

18 A. Correct.

19 Q. What's an exogenous source?

20 A. Exogenous source is a source outside of
21 the patient.

22 Q. What's --

23 A. And then part of that is based upon my
24 experience over 23 years at CDC. We -- I was in
25 charge of the outbreak investigation group for 17

Page 151

1 Q. Well, that would be true of the Bair
2 Hugger as well; right? The Bair Hugger itself even
3 in your formulation doesn't cause the infection --

4 MR. B. GORDON: Object to the form.

5 BY MR. C. GORDON:

6 Q. -- it would be the pathogen; right?

7 MR. B. GORDON: Calls for a legal
8 conclusion. Object to the form.

9 THE WITNESS: Well, it absolutely depends
10 upon the pathogen. The difference is that the
11 characteristics that we're talking about, most of
12 the characteristics in terms of risk factors, you
13 know, enhance the likelihood of infection giving
14 contamination; whereas, in the case of the Bair
15 Hugger, it's actually a source of the organisms.

16 BY MR. C. GORDON:

17 Q. So you're distinguishing between source
18 and -- what -- how would you characterize
19 patient-specific factors if they're not sources?

20 A. Risk factors. So there's risk factors
21 enhance the likelihood that if contamination were
22 occur [as said]. But if you're a diabetic, that
23 doesn't increase the likelihood that you have a bug
24 in your wound. Diabetes doesn't produce any bugs in
25 your wound. Diabetes just makes it if you get a bug

Page 153

1 years. We investigated more outbreaks than anyone
2 on this planet. And of the surgical site infection
3 outbreaks that we investigated, almost all of them
4 were due to exogenous sources. There was one that
5 was due to a patient source.

6 Q. What's the opposite of an exogenous
7 source?

8 A. Endogenous.

9 Q. Okay. So my -- I guess my question is are
10 there any patient-specific risk factors that
11 increase the endogenous sources of bacteria?

12 A. I'm trying to think if there's any studies
13 that have been done to really answer that question.
14 There certainly have been studies that have looked
15 at different patient populations to see who's
16 colonized, who's not colonized, even some studies
17 looking at the degree of colonization in one
18 location to the other. But I don't know that they
19 address your specific question.

20 Q. What years were you at the CDC?

21 A. 1980 to 2003.

22 Q. So by the time you supervised the
23 preparation of the 1999 surgical site guidelines,
24 Exhibit 5, you had already been at the CDC almost
25 two decades; right?

Page 154

1 A. 19. Well, I probably started at least two
2 years before that. But, yeah, over 15 years.

3 Q. Okay. And going back to the sentence
4 where -- in your report where you say, "Exogenous
5 sources account for the majority of SSIs," you
6 didn't actually cite any medical literature for that
7 proposition, did you?

8 A. No.

9 Q. You just said -- that was based on your
10 years of experience at the CDC; right?

11 A. That was based on the outbreaks that we
12 investigated when I was at CDC, as well as
13 scientific literature.

14 Q. Could you turn on Exhibit 5 to page 103.
15 Direct your attention to the first full paragraph on
16 that page. Could you read that first full sentence.

17 A. The first full sentence?

18 Q. Beginning with, "For most SSIs."

19 A. "For most SSIs, a source of pathogens is
20 the endogenous flora of the patient's skin, mucous
21 membranes, or hollow viscera."

22 Q. And for that there's a citation; correct?

23 A. Correct. A study from 1968.

24 Q. The Altameier, Culbertson, and Hummel
25 study?

Page 155

1 A. No. Actually --

2 Q. Did I get that wrong?

3 A. Oh. 57. Yes, yes. Right. 1968, right.

4 Q. So the sentence in your 1999 CDC guideline
5 says, "Most pathogens are endogenous." And in your
6 report you say "most are exogenous." Right?

7 A. Right. And the --

8 Q. Did something happen in the last four
9 years of your CDC tenure to make you change your
10 mind about everything you learned in the first 19?

11 MR. B. GORDON: Objection to form.
12 Mischaracterizes the evidence. And argumentative.

13 THE WITNESS: Well, couple of things. One
14 is it talks about endogenous. And then it talks
15 also about exogenous organisms as a source of SSI
16 include surgical personnel; operating room
17 environment; all tools, instruments, materials
18 brought to the sterile field during the operation.
19 So it doesn't exclude those.

20 But if you look at what happened between
21 this guideline -- and, actually, it started a little
22 bit before this guideline -- but a tremendous number
23 of interventions have been applied to patients to
24 reduce the endogenous flora and the importance of
25 the endogenous flora. Most of the Center for

Page 156

1 Medicare/Medicaid services or CMS -- what's called
2 SCIP measures -- which is a surgical care
3 improvement -- surgical infection prevention.

4 Activities were really focused at the
5 endogenous rather than exogenous flora. So, for
6 instance, improvement of prophylactic antibiotics,
7 improvement in skin antisepsis by the use of
8 chlorhexidine alcohol rather than povidone iodine.

9 (Reporter asks for repetition.)

10 "Chlorhexidine alcohol rather than
11 povidone iodine."

12 Those activities were really aimed at the
13 endogenous flora. So there's really a lot of
14 activities on endogenous flora; not as many
15 necessarily on the exogenous flora.

16 BY MR. C. GORDON:

17 Q. Okay. So as of 1999 you were satisfied
18 that the state of the medical literature was such
19 that you could say that the majority of SSIs were
20 caused by endogenous flora; right?

21 A. Right. As endemic infections, yes.

22 Q. And that's changed in the last 18 years
23 for the reasons you mentioned; right?

24 A. Correct.

25 Q. Are you aware of any medical journal,

Page 157

1 textbook, anything in the last 18 years that has
2 said what you say, which is that the majority of
3 SSIs are caused by exogenous sources?

4 A. Well, certainly the Seminars journal that
5 we gave you a copy of that gives a list of all the
6 outbreaks that CDC did as well as the role of the
7 environment. There's a number of papers in that
8 that document the role of exogenous sources of
9 infection.

10 Q. My question is very specific. You were
11 satisfied in 1999 that the majority were caused by
12 endogenous sources. And you actually cited one
13 published paper for that. In the 18 years since the
14 1999 guidelines were published, has any medical
15 journal or textbook published any kind of a
16 conclusion -- study, metanalysis, anything -- that
17 concludes that now things have shifted so such that
18 the majority of SSIs are exogenous?

19 MR. B. GORDON: Object to form; asked and
20 answered.

21 THE WITNESS: Well, I don't know that I've
22 done a search for, you know, every -- it wouldn't --
23 Medline search wouldn't pick up books anyway. But
24 I'm not sure I've seen a specific paper looking at
25 that.

Page 158

1 As I say, the Seminars journal that we
2 gave you shows all the CDC outbreaks that we
3 investigated and the surgical site outbreaks in
4 particular. Of the 22, 20 of the 22 -- actually, 21
5 of the 22 are exogenous sources of infection. The
6 reference that we gave here is 1968. So it probably
7 was changing even at this time.

8 BY MR. C. GORDON:

9 Q. Is the CDC called in for -- every time
10 there's a surgical site infection?

11 A. I doubt it. They'd be kind of busy if
12 they were. No.

13 Q. In fact, the CDC is not called in for the
14 overwhelming majority of surgical site infections
15 that occur every day and throughout the country;
16 right?

17 A. Absolutely. Or healthcare-associated
18 infections in general. And they have to be very
19 specific in what they investigate. And we try to
20 pick outbreaks that would advance the field of
21 infection control and not be redundant of something
22 that's been shown 20 times.

23 Q. Okay. So if patients are experiencing
24 common surgical site infections that arise from
25 endogenous flora that have been studied many times

Page 159

1 over the years, that would probably not be something
2 that would result in a CDC outbreak investigation?

3 MR. B. GORDON: Object to form.

4 BY MR. C. GORDON:

5 Q. Right?

6 MR. B. GORDON: Lack of foundation. Calls
7 for speculation.

8 THE WITNESS: Well and that's probably not
9 true. It depends on the organism. For instance,
10 like the heater-cooler investigation was a very
11 unusual organism. Very similar to what we're
12 dealing with here with Bair Hugger where it was a
13 device that was used for decades and thought to be
14 perfectly safe. That then only was recognized as
15 being a cause of infection because Mycobacterium
16 chimaera infections were occurring in cardiac
17 surgery patients. And that was very unusual. So
18 certainly if the heater coolers have been associated
19 with Staph aureus infections it probably would have
20 taken a lot longer before it would have been
21 recognized.

22 BY MR. C. GORDON:

23 Q. And my question went to garden variety
24 infections. Let's take Staph epidermidis. That's a
25 pretty common surgical site infection; isn't it?

Page 160

1 A. Correct.

2 Q. And probably everybody in this room has
3 Staph epidermitis bacteria; right?

4 A. Correct.

5 Q. Some maybe more than others.

6 A. Possibly.

7 MR. ASSAAD: For the record Corey Gordon
8 just looked directly right at Mr. Assaad, which is
9 myself, talking about Staph epidermis.

10 MR. C. GORDON: Are you feeling guilty?
11 Sorry.

12 MR. ASSAAD: A little bit. I didn't take
13 a shower this morning, so it might be less than
14 most.

15 BY MR. C. GORDON:

16 Q. So a hospital experience as a single
17 surgical site infection involving Staph epidermitis,
18 that wouldn't be the type of thing that would result
19 in CDC getting a call and starting an outbreak
20 investigation; right?

21 MR. B. GORDON: Object to the form. Calls
22 for speculation, the source of the outbreak.

23 THE WITNESS: Well, if it was the
24 infecting pathogen, I think it's probably unlikely
25 that it would lead to a CDC investigation. On the

Page 161

1 other hand, if it were Staph epidermitis that had a
2 very unusual antibiogram, for instance, so --

3 (Reporter asks for repetition.)

4 Antibiogram. So, for instance, when the
5 first reported Staph aureus or MRSA that had
6 vancomycin intermediate resistance --

7 (Reporter asks for repetition.)

8 Vancomycin intermediate resistance occur
9 it was N of 1. And we investigated to try to
10 identify what was going on.

11 Now, if it had been an MRSA or a Staph
12 aureus with a very common antibiotic susceptibility
13 pattern, we wouldn't have investigated probably.

14 BY MR. C. GORDON:

15 Q. And take away from that what the CDC
16 investigates is unusual circumstances. A cluster of
17 more infections than you would normally expect for
18 an unusual type of pathogen.

19 MR. B. GORDON: No question yet.

20 BY MR. C. GORDON:

21 Q. Right?

22 MR. B. GORDON: Object to the form.

23 THE WITNESS: Well, it's a combination of
24 factors. So it's unusual -- or I mean, it's an
25 unusual antibiogram association with a medical

<p style="text-align: right;">Page 162</p> <p>1 device that's not been known to be a source before 2 like the heater-cooler. So there's a list of 3 different possibilities of what would be 4 investigated. But certainly every infection that 5 occurs would not be investigated. 6 BY MR. C. GORDON: 7 Q. So the fact that 20 of the 21 8 investigations that you referred to that the CDC 9 investigator proved to be exogenous sources, are you 10 saying that that tells you that all the infections 11 that you didn't investigate must also be 12 predominantly exogenous? 13 MR. B. GORDON: Objection to form. 14 Misstates his testimony. 15 THE WITNESS: Yeah, I wouldn't say it 16 necessarily is -- is -- reflects that. But it does 17 show that even though many of those were Staph 18 aureus infections and some like Dr. Wenzel would say 19 that's exogenous organisms. In fact, when we 20 investigated them, they weren't. And without 21 investigating them, you don't know. 22 BY MR. C. GORDON: 23 Q. I go back to my earlier question. Can you 24 point me to any published medical literature in the 25 last 18 years that says that now the majority of</p>	<p style="text-align: right;">Page 163</p> <p>1 SSIs are caused by exogenous sources? 2 MR. B. GORDON: Objection; asked and 3 answered. 4 THE WITNESS: As I mentioned, that 5 Seminars in Infection Control has a number of papers 6 in there that would address that. I'm sure there 7 are others in the published literature talking about 8 the relative relationship between endogenous and 9 exogenous sources. 10 BY MR. C. GORDON: 11 Q. When you say you're sure there are, have 12 you done research to see if that's the case? 13 A. I have not looked recently. It would be 14 pretty easy to do. 15 Q. But you didn't do that? 16 A. No. 17 Q. So when you said on page 5 of your report, 18 "Exogenous sources account for the majority of 19 SSIs," that was based on your own personal analysis; 20 right? 21 A. Well, personal analysis as well as 22 experience at CDC investigating outbreaks for 17 23 years. 24 Q. Well, you had had that experience in 1999 25 when you wrote, "For most SSIs, the source of</p>
<p style="text-align: right;">Page 164</p> <p>1 pathogens is the endogenous flora of the patient's 2 skin"; right? 3 A. Well, I hadn't had it all in 1999. I had 4 been there -- what? -- 19 -- 17 years probably when 5 I started. It had been 19 years. 6 Q. Okay. And so -- 7 A. So it was changing. And that is a 8 reference from 1968, which is a few years before 9 that. 10 Q. Well, in 1999 when you were applying the 11 CDC gold standard methodology, I assume you took 12 note of the fact that some study you were citing was 13 1968 and you would have done at least some research 14 to see if that was still a valid study or if there 15 were more contemporary things that called that into 16 question; right? 17 A. I'm sure there was some literature 18 reviewed, yes. 19 Q. And if you had found something post 1968, 20 which challenged the statement that you put out in 21 these guidelines, you would have at least considered 22 it and perhaps mentioned it; right? 23 A. Well, we do mention in the next paragraph. 24 It basically is a paragraph on endogenous and a 25 paragraph on exogenous.</p>	<p style="text-align: right;">Page 165</p> <p>1 Q. Okay. I'm talking -- and again I 2 understand there -- you talk about exogenous and 3 endogenous. 4 You would agree with me that what you say 5 in 1999 says that "more than 50 percent of SSIs are 6 caused by endogenous sources." What you're saying 7 now in this expert report is that more than 8 50 percent of SSIs are caused by exogenous sources; 9 right? 10 MR. B. GORDON: Objection to form. And 11 you're misquoting the citation you're referring to 12 now, Corey. You're using "causes" instead of 13 "sources." And before you were saying "sources." 14 So just be clear for the record exactly what you're 15 asking him. 16 BY MR. C. GORDON: 17 Q. And I'll accept that as a friendly 18 amendment. My question relates to "sources," not 19 "causes." 20 A. Okay. I think what we were trying to do 21 in the SSI guideline is basically point out that 22 both endogenous and exogenous sources of pathogens 23 are important in patients undergoing SSIs. 24 The other thing is that this guideline is 25 a guideline for all SSIs, not specific to prosthetic</p>

Page 166

1 joint infections. And so there's a difference there
2 as well. We're not talking specifically about
3 prosthetic joints. We're talking about all SSIs.

4 Q. Okay. Let's look at the very next
5 sentence. I'm sorry. Not the very next sentence.
6 Couple of sentences down where you talk about
7 seeding of the operative site from a distant focus
8 of infection. Do you see that?

9 A. No. Which page are we in?

10 Q. It's on page 103. It's on the
11 right-hand -- top of the right-hand column. I'm
12 sorry. On the 1999 guidelines. Exhibit 5. The
13 paragraph on endogenous sources. Towards the end
14 you're talking about seeding of the operative site
15 from a distant focus of infection.

16 A. Right.

17 Q. That would be an endogenous source; right?

18 A. Well, seeding could be endogenous or
19 exogenous.

20 Q. Okay. What is seeding? What does that
21 mean?

22 A. Basically means there's a source of the
23 organism and the organism then gets in from that
24 source into the prosthetic joint.

25 Q. So how could there be an exogenous

Page 167

1 seeding?

2 A. Well, it could be like the Bair Hugger
3 where it's blowing contaminated air or excess heat
4 is changing the ventilation with convection and
5 bringing organisms from the flora. That would be
6 seeding. Seeding is basically that the organism
7 gets into the wound.

8 Q. What is -- I'm sorry. What is -- what
9 does the phrase "distant focus of infection" mean in
10 that sentence?

11 A. Well, that particular sentence, "seeding
12 of the operation site from a distant focus of
13 infection," is talking specifically about patients
14 that would have, say, an abscess somewhere else,
15 would be one possibility; other would be
16 colonization.

17 Q. All endogenous; right?

18 A. Those would be endogenous, yes.

19 Q. All what the patient brings to the table;
20 right?

21 A. That's one possibility, yes.

22 Q. Okay. And in 1999, you said that that
23 seeding from distant focuses of infection was
24 particularly -- occurred particularly in patients
25 who have a prosthesis or other implanted -- implant

Page 168

1 placed during the operation; right?

2 A. Correct.

3 Q. And so you -- in that particular sentence
4 there's no question in your mind, you're saying that
5 this issue of seeding from a distant focus of
6 infection, that can cause SSIs but particularly can
7 cause SSIs in cases -- in the case of implants;
8 right?

9 MR. B. GORDON: Objection to form,
10 counsel's characterization of cause which is source.

11 THE WITNESS: Well, if you look at most of
12 the references, most of the references are talking
13 about patients who have had a bacteremia. So one is
14 prosthetic valve endocarditis. Another one is about
15 hematogenous spread of bacteria. Another one is
16 about bacteremia. So they're not really talking, in
17 terms of references, about a patient who happens to
18 be colonized with Staph aureus and gets a Staph
19 aureus infection. They're virtually all -- let's
20 see. Most of them are secondary to bacteremia.

21 BY MR. C. GORDON:

22 Q. What's reference number 60? What's that
23 about?

24 A. Well, I think reference 60 is talking
25 about the important role of prophylactic

Page 169

1 antibiotics; in this case, hip replacement
2 procedures.

3 Q. Well, how does it support the statement
4 that you made that "seeding of the operative site
5 from a distant focus of infection can be another
6 source of SSI pathogens"?

7 A. Well, I'd have to go back and pull that
8 paper. But my guess is that that one is showing
9 that if prophylactic antibiotics are given as the
10 right drug at the right time at the right dose, that
11 they reduce the risk for infection even if you have
12 a bacteremia or other endogenous source. Or even
13 exogenous source.

(Exhibit 16 marked.)

15 BY MR. C. GORDON:

16 Q. Show you Exhibit 16. Is that the cite?

17 MR. B. GORDON: Can I have a copy?

18 MR. C. GORDON: No. Sorry. I don't have
19 one.

20 THE WITNESS: (Witness reviews document.)
21 Okay.

22 MR. C. GORDON: Was there a -- was there a
23 question pending? Or the question right before he
24 said he had to look at the study.

25 (Record read as follows:

Page 170

1 "Q. Well, how does it support the
2 statement that you made that 'seeding of
3 the operative site from a distant focus
4 of infection can be another source of
5 SSI pathogens'?"

6 THE WITNESS: As I say, I think they were
7 specifically looking at -- in this paper at the role
8 of prophylactic antibiotics. And it seems like they
9 were also talking about the fact -- at least there's
10 mention of the fact -- that the wound is -- where
11 did they say it?

12 So they don't really say that much about
13 the source. They really in this paper are looking
14 at early infections versus late infections and
15 whether the prophylactic antibiotic has an impact on
16 both.

17 BY MR. C. GORDON:

18 Q. Let's go back to Exhibit 5, the 1999
19 guideline. Still on page 103. Back to the
20 beginning of that paragraph on endogenous sources.
21 In the second sentence you say, "When mucous
22 membranes or skin is incised, the exposed tissues
23 are at risk for contamination for endogenous flora."

24 Did I read that correctly?

25 A. You did.

Page 172

1 you would recommend not be done for orthopedic
2 implant patients? Any of the things you just
3 mentioned as part of the SSI prevention bundles?

4 A. I think they're all important, but there
5 are some areas of debate or controversy.

6 Q. When the -- well, let's back up.

7 When you prepare the skin, whether its
8 chlorhexidine or povidone iodine or whatever, all it
9 can do is decontaminate the surface layer of the
10 skin; right?

11 A. Well, its primary impact is on the
12 transient flora; correct.

13 Q. Well, there can be transient flora that
14 are -- that are in the hair follicles or sebaceous
15 glands; right?

16 MR. B. GORDON: Object to the form.

17 THE WITNESS: They definitely can be. And
18 some of those are removed and some are not.

19 BY MR. C. GORDON:

20 Q. Is that one of the reasons why you -- and
21 I there's actually unanimity in the -- among all of
22 the experts in this case that chlorhexidine
23 gluconate is the preferred skin prep for surgery
24 because it can --

25 A. Well, I would say chlorhexidine with

Page 171

1 Q. What does that mean?

2 A. Means that the patient's own skin flora
3 can be a source of contamination and that's why we
4 emphasize the importance of chlorhexidine bathing
5 before surgical procedures in use of chlorhexidine
6 with alcohol preferably for skin prep. And, as that
7 paper shows, the importance of prophylactic
8 antibiotics and reducing the risk of those
9 infections from occurring.

10 So that whole part of what's now called
11 SSI prevention bundles are really aimed at
12 preventing those endogenous infections or infections
13 from a patient's own flora. It also gets to
14 potentially screening for MRSA or MMSA and
15 decolonization with mupirocin and, again,
16 chlorhexidine.

17 (Reporter asks for repetition.)

18 Decolonization with mupirocin --
19 M-U-P-I-R-O-C-I-N. Chlorhexidine.

20 Q. All of those things can have a beneficial
21 impact on the risk of a joint infection; right?

22 A. Well, some are proven more than others.
23 But the aim of those things is to reduce the impact
24 of endogenous flora and causing infections.

25 Q. Are there any -- any of those things that

Page 173

1 alcohol.

2 (Reporter asks for repetition.)

3 Chlorhexidine with alcohol. Because
4 alcohol has an immediate effect and chlorhexidine
5 has an immediate and a long-term effect.

6 (Reporter asks for repetition.)

7 Chlorhexidine with alcohol. Because
8 alcohol has an immediate effect and chlorhexidine
9 has both an immediate and long-term effect.

10 Q. Is part of the long-term effect associated
11 with chlorhexidine the fact that it may get down
12 into hair follicles and sebaceous glands over time?

13 A. Yeah, I don't know how good those data
14 actually are. Primary reason for chlorhexidine
15 having benefit over, say, povidone iodine is --

16 (Reporter asks for repetition.)

17 -- povidone iodine is that chlorhexidine's
18 spectrum of activity is better for gram-positive
19 organisms; whereas, povidone iodine activity is
20 better for gram-negative organisms.

21 Povidone iodine is inactivated by
22 proteinaceous material. Chlorhexidine is not. And
23 chlorhexidine binds to the skin. So the fact that
24 you have blood and proteinaceous material during a
25 surgical procedure makes chlorhexidine preferable to

Page 174

1 povidone iodine.

2 I'm not sure that there are any data that
3 it actually seeps into the hair follicles and
4 sebaceous glands and reduces those organisms more,
5 but they certainly would have binding of the skin.
6 And so it has a longer impact than something like
7 povidone iodine that you put on and, basically, if
8 it has contact with proteinaceous material, it's
9 inactivated and done with.

10 Q. So would povidone iodine be effective
11 against Staph aureus?

12 A. It can be. But chlorhexidine probably has
13 better activity.

14 Q. So if an orthopedic implant patient is
15 prepped with povidone iodine, there's a greater risk
16 that they're going to have residual Staph aureus on
17 their skin than if they're prepped with
18 chlorhexidine?

19 MR. B. GORDON: Object to the form --
20 BY MR. C. GORDON:

21 Q. Perhaps?

22 MR. B. GORDON: -- counsel's testimony.

23 THE WITNESS: Well, I think you have to
24 look at, number one, is it povidone iodine alone, or
25 is it povidone iodine with alcohol? Because alcohol

Page 175

1 obviously has an immediate effect. And most of the
2 studies looking at either skin prep or surgical prep
3 with chlorhexidine versus povidone iodine, were
4 chlorhexidine with alcohol versus povidone iodine
5 without alcohol. So it's two agents on one side and
6 one on the other; so it's kind of a little bit
7 unfair.

8 As far as I know, there's only been one
9 randomized control trial of chlorhexidine with
10 alcohol versus povidone iodine with alcohol. And
11 that was with catheter and -- vascular catheter
12 insertion. Where chlorhexidine with alcohol was
13 found to be superior.

14 There's actually one before/after study at
15 Dr. Wenzel's former hospital, University of
16 Virginia, looking at povidone iodine with alcohol
17 versus chlorhexidine with alcohol. It showed
18 chlorhexidine with alcohol was superior.

19 Q. Would you agree that the more bacteria you
20 remove from the skin, the less chance there is of
21 re- -- any residual bacteria migrating into the site
22 once the skin has been incised in -- in joint
23 surgery?

24 MR. B. GORDON: Object to the form. Lack
25 of foundation.

Page 176

1 THE WITNESS: I think that might be a --
2 kind of a commonsense belief. Chuck Edmondson has
3 done a lot of studies of chlorhexidine as a skin
4 prep. And talking to him a couple of weeks ago, his
5 belief is that actually two applications is
6 sufficient and not that, you know, if you did five
7 applications you'd be better.

8 BY MR. C. GORDON:

9 Q. Again, I -- sorry. I moved on beyond the
10 issue of what's the better -- what's the best skin
11 prep. My question goes to the -- just the number of
12 bacteria on a person's skin.

13 A. But that's --

14 Q. All other things being equal, if there --
15 if person X has more bacteria on his skin than
16 person Y, person X is at greater risk of a joint --
17 a PJI than person Y --

18 MR. B. GORDON: Object to the form --
19 BY MR. C. GORDON:

20 Q. -- from those bacteria; right?

21 MR. B. GORDON: Object to the form and
22 counsel's preamble.

23 THE WITNESS: Yeah, I guess I would say
24 that as this document, the guideline, states, there
25 is endogenous organisms and there's exogenous

Page 177

1 organisms. And you and Dr. Wenzel are ignoring
2 totally the exogenous. And I would say that
3 regardless of how many bugs you have on your skin,
4 if you're going -- undergoing a prosthetic joint
5 procedure, if there are two people in the room
6 versus there are 10 people in the room, that's
7 probably a much more important factor. You're not
8 jumping around; they are. You're not having your
9 skin squames -- S-Q-U-A-M-E-S -- being aerosolized
10 all over the place.

11 You as the patient having surgery have had
12 hopefully chlohexadine baths, you had chlorhexidine
13 with alcohol or some good skin prep that's killed a
14 lot of the bugs that you have on you. Whereas, all
15 those people around you in the surgical procedure
16 have not had any of that and are disseminating
17 organisms.

18 And that's why a device like the Bair
19 Hugger, when it has all that heat that's being
20 released underneath the operating room table and has
21 the possibility with convection currents to bring
22 that up over the operative field, that exogenous
23 source ends up being more important than the
24 endogenous source.

25 MR. C. GORDON: Move to strike as

Page 178

1 nonresponsive.

2 Q. Again, all I'm asking is -- about
3 comparing one patient to another, everything else
4 being equal. If patient X has more bacteria on his
5 skin at the site of the incision than patient Y,
6 patient X is at a greater risk of a deep joint
7 infection than patient Y --

8 MR. B. GORDON: Object to --

9 BY MR. C. GORDON:

10 Q. -- from those bacteria; right?

11 MR. B. GORDON: Object to form. And asked
12 and answered.

13 THE WITNESS: I guess I would say that
14 might be theoretically true; I'm not aware of any
15 study that's done that. It's actually a very
16 difficult study to do. You'd have to do
17 quantitative counts on the skin of the patient.
18 You'd have to do those by species. And that's a
19 very difficult study, very expensive study to do.
20 And I don't know of any data that has -- any study
21 that's done that and, in addition to doing that, has
22 also followed those patients for surgical deep joint
23 prosthetic joint infections and done genomic typing
24 and correlated the two. And you would really have
25 to do that to answer that question.

Page 180

1 MR. B. GORDON: Objection to form.

2 Assumes facts not in evidence.

3 BY MR. C. GORDON:

4 Q. Does the Ioban drape kill all those bugs
5 too?

6 A. They don't maybe kill all of those bugs,
7 but they are basically minimizing the amount of
8 exposure that the wound has to skin, period.

9 Q. So help me understand what you are saying
10 here. In Exhibit 5, "When mucous membranes or skin
11 is incised, the exposed tissues are at risk for
12 contamination with endogenous flora."

13 A. I think that goes back to that 1968
14 article and basically talking about organisms that
15 are on the patient's skin.

16 Q. Actually that particular statement goes
17 back to a 1978 article; right?

18 MR. B. GORDON: '79.

19 MR. C. GORDON: '79.

20 THE WITNESS: Thank you. At 58 or 56?

21 MR. ASSAAD: Hey, Corey? Maybe we can
22 take a break. Don't forget about what the court
23 reporter needs. With all these words, she might
24 need a break at some point.

25 MR. C. GORDON: Mr. Staph Epidermis [sic]

Page 179

1 BY MR. C. GORDON:

2 Q. Skin -- or -- strike that.

3 Bacteria that remain on the skin after
4 skin prep, if they're right at the site of incision,
5 can migrate to the joint implant; right?

6 MR. B. GORDON: Objection to form.
7 Assumes facts not in evidence. Lack of foundation.

8 THE WITNESS: Again, it's theoretically
9 possible. But if they're using something like an
10 Ioban drape, you've basically covered that whole
11 area --

12 (Reporter asks for repetition.)

13 Ioban, I-O-B-A-N.

14 Where you have basically a povidone
15 iodine-impregnated plastic sheet that's going over
16 the patient and doing an incision through it. So
17 you literally have almost no skin that has any
18 exposure to the operative site. So if you had tons
19 of bugs versus no bugs, how -- what are they going
20 to do, jump through the plastic sheet and jump
21 around? They can't.

22 BY MR. C. GORDON:

23 Q. I'm talking about the residual bacteria in
24 the sebaceous glands in the hair follicles and the
25 lower dermal layers.

Page 181

1 wants a break. So --

2 MR. ASSAAD: I don't need a break at all.
3 I just -- I feel that she's been having trouble with
4 all these words; she might need a break.

5 MR. B. GORDON: You don't have to take all
6 this down. This is off the record.

7 If you want.

8 MR. C. GORDON: Yeah, that's fine.

9 Heidi, did you need a break?

10 THE REPORTER: Yeah, that would be great.

11 THE VIDEOGRAPHER: The time is 2:01 p.m.
12 We are off the record.

13 (Recess taken from 2:01 p.m. to 2:12 p.m.)

14 THE VIDEOGRAPHER: This marks the
15 beginning of Volume I, file 4 in the deposition of
16 Dr. William Jarvis. The time is 2:12 p.m. and
17 we're on the record.

18 BY MR. C. GORDON:

19 Q. Dr. Jarvis, just to be clear, have you
20 written anything other than your expert report,
21 Exhibit 1, since you did the CDC guidelines in 1999
22 where you have concluded that exogenous sources now
23 account for the majority of SSIs?

24 A. I certainly have written many, many things
25 since 1999 regarding surgical site infections. I

Page 182

1 would have to look and see if I have that specific
2 sentence in them or not. Certainly the Seminars in
3 Infection Control have an entire paper on the role
4 of environment. So --

5 (Exhibit 17 marked.)

6 BY MR. C. GORDON:

7 Q. Okay. I'm going to -- just so the record
8 is clear, I'm going to give you Exhibit 17. Is that
9 the infection control paper you've been referring
10 to? Or you just referred to?

11 A. (Witness reviews document.)

12 Q. Is it -- is that Exhibit -- what was it,
13 17? Is that the one you were just talking about?

14 A. Yes.

15 Q. Okay. Is the -- what chapter is it that
16 you said dealt with -- was it environmental factors?

17 A. Well, outbreaks associated with
18 environment and outbreaks associated with medical
19 devices and medications. Both talk about exogenous
20 sources.

21 Q. Okay. Let's start with outbreaks
22 associated with the environment on page 1- --
23 starting on page 124.

24 You -- you were one of the authors of this
25 chapter; correct?

Page 183

1 A. Correct.

2 Q. Okay. And under "Air," could you list off
3 the infectious pathogens that you discuss.

4 A. Well, we talked specifically about
5 outbreaks. So TB, measles, varicella, potential
6 bioterrorism agent such as smallpox, influenza,
7 Legionnaires, Pontiac fever.

8 Q. Okay.

9 A. So those are the ones that we focused on
10 because of the fact that they were associated with
11 outbreaks, as well as fungal infections.

12 Q. Right. And just -- I'm curious. You
13 know, you wrote it, so you tell me. Is there
14 anything else in this chapter that talks about
15 airborne pathogens that could -- could relate to
16 peri-prosthetic joint infections?

17 A. Well, it also talks about MRSA on page
18 127.

19 And under "Prevention" it talks about
20 adequate installation, regular monitoring,
21 preventive maintenance of HVAC systems are required
22 to ensure that systems function -- function properly
23 and minimize the risk of pathogen transmission to
24 patients and staff. So there's a whole paragraph
25 talking -- two paragraphs, actually, talking about

Page 184

1 the importance of HVAC systems in preventing
2 infection, but it doesn't specifically mention
3 prosthetic joints.

4 Q. Well, in -- on page 127 where you talk
5 about MRSA, what is the mode of transmission you
6 discuss? Or the mode of spread? Excuse me.

7 A. Airborne spread?

8 Q. Yes.

9 MR. B. GORDON: I think he answered you,
10 Corey.

11 BY MR. C. GORDON:

12 Q. Just ventilation; right?

13 A. Well, it talks about the fact that MRSA
14 has been documented to be spread by the airborne
15 route.

16 Q. From ventilation; correct?

17 A. Correct.

18 Q. That's --

19 A. Ventilation grilles, exhaust.

20 Q. Ventilation grilles and exhaust ducts;
21 right?

22 A. Right.

23 Q. And you note that other well-established
24 modes of transpor- -- transmission such as transient
25 hand carriage by healthcare workers were not

Page 185

1 investigated or eliminated; is that correct?

2 A. Correct.

3 Q. So is -- would you agree that there are
4 other well-established modes of transmission of
5 Staph aureus?

6 A. Oh, absolutely, yeah. On hand
7 transmission as well as being aerosolized from
8 patients to other patients, as well as in the
9 operating room.

10 Q. When CDC would do an outbreak
11 investigation, how would you go about assessing
12 whether the outbreaks were coming from any of the
13 well-established modes of transmission?

14 A. Well, it was part of that gold standard
15 approach that I talked about. So it would be, you
16 know, reviewing cases, doing line listings, doing
17 epidemiologic studies to look at risk factors. And
18 then based on that epidemiologic data, doing either
19 personnel or environmental cultures. Looking at a
20 variety of potential sources. And then probably
21 doing molecular typing of the organisms to see if
22 they were the same or not.

23 Q. And the reason you do that or would do
24 that for joint infections is that there are a myriad
25 of potential sources; right?

Page 186

1 MR. B. GORDON: Objection to the form.
2 Also mischaracterization.

3 THE WITNESS: Well, there are certainly
4 many endogenous and exogenous source possibilities.
5 Some of which are -- or many of which you hopefully
6 can eliminate.

7 BY MR. C. GORDON:

8 Q. And the only way you can eliminate them is
9 if you investigate them; right?

10 MR. B. GORDON: Object to the form.

11 THE WITNESS: Well, you can do -- it
12 depends on if it's a cluster or an individual case.
13 Obviously if it's a cluster, trying to do an
14 epidemiologic study can assist you in identifying
15 whether it's personnel that are the source or
16 potentially the patient or equipment.

17 BY MR. C. GORDON:

18 Q. And how do you do that in an individual
19 case?

20 A. It's a little bit more difficult, but you
21 look -- I think in the individual case, you also
22 focus on kind of the timeline of events of what has
23 happened and looking at all the different prevention
24 interventions, some of which we've talked about such
25 as skin prep, timing of prophylactic antibiotics,

Page 188

1 listing, epidemiologic studies to try to identify
2 what the risk factors for infection are. And there
3 certainly would be some ways to try to address that.
4 It's obviously -- if the outbreak is ongoing, and
5 it's probably easier to do than if the outbreak
6 stopped two weeks ago. So it's a little -- the type
7 of the investigation tends to be tailored to the
8 specific outbreak and the timing of that outbreak
9 and what's available, what's not as to what you can
10 do.

11 Q. How do you define an outbreak?

12 A. Well, I think the generally accepted
13 definition is it's the frequency of occurrence of an
14 event that is above the baseline rate and reaches a
15 statistical significance. And that's usually the
16 definition that is used. And there is somewhat a
17 differentiation of "epidemic" or "outbreak" from
18 "endemic." So a lot of the infections that occur
19 are endemic infections, particularly if it's a
20 patient's own endogenous flora.

21 And so if you look at a hospital within,
22 say, MRSA infection rate, they've got a long period
23 of time where they've had MRSA infections and
24 there's some kind of background rate of what that
25 is. With an outbreak, it assumes that you have that

Page 187

1 breaks in aseptic technique, the duration of the
2 procedure. So a lot of individual factors that may
3 either increase or decrease the risk for infection
4 occurring.

5 MR. B. GORDON: For the record I want to
6 interpose an objection here.

7 I'll give you some latitude, Corey, but
8 we're to talk about general causation today. There
9 is a thing contemplated the other day for
10 case-specific causation. Will be a different
11 report, different deposition. But if you want to
12 ask those questions today, then we're going to take
13 the position that you're done after today.

14 BY MR. C. GORDON:

15 Q. Going back to -- I want to look back on
16 page 127 where you talk about other well-established
17 modes of transmission such as transient hand
18 carriage by healthcare workers. How could you --
19 how -- what was your -- what -- strike that.

20 You -- you do say here that in outbreaks
21 those were not investigated or eliminated. Would
22 there have been a methodology for investigating or
23 eliminating those?

24 A. Well, you could follow the same pattern
25 of, you know, medical record review, and line

Page 189

1 background rate or can calculate that background
2 rate and then look at what the rate of event is
3 during a putative outbreak period and then do a
4 statistical analysis to see if the rate is increased
5 statistically.

6 Q. One of the papers that you rely on for
7 your opinion is the McGovern 2011 study. We talked
8 a little bit about it earlier. It had bubble
9 component to it. And it also had a -- an
10 observational study component to it; correct --

11 MR. B. GORDON: Object to the form --
12 BY MR. C. GORDON:

13 Q. -- do you agree?

14 MR. B. GORDON: -- counsel's use of the
15 word "reliance" -- "reliance" or "relied on,"
16 something like that.

17 What's the question?

18 BY MR. C. GORDON:

19 Q. Well --

20 A. The question was whether they had two
21 components or not?

22 Q. Do you rely on the McGovern study?

23 MR. B. GORDON: Objection to counsel's
24 characterization, use of the word "rely."

25 THE WITNESS: As I said before, I look at

Page 190

1 all of the papers that I've read, my experience; you
2 know, 23 years at CDC, both in terms of outbreak
3 investigations, developing surveillance definitions,
4 assisting with the development of the surveillance
5 system and knowing surveillance data. All of that
6 is incorporated in how I look at the data and how I
7 reach the conclusions in my report. So certainly
8 the Albrecht study was one of many that I looked at
9 that --

10 BY MR. C. GORDON:

11 Q. You mean the McGovern -- well, Albrecht
12 was an author. You're talking about McGovern?

13 A. McGovern was one of many that I referenced
14 in my report.

15 Q. Was there any other study that you
16 referenced in your report that purported to show a
17 relative risk of Bair Hugger versus some other
18 warming modality in terms of joint infections?

19 A. No. That was -- that was the solid one.

20 Q. So you -- before -- I assume before you
21 decided whether that was something worthy of your
22 inclusion in your report, you wanted to -- see if I
23 can find your exact phrase -- you wanted to look
24 critically and evaluate all the data, not just some
25 of the data; right?

Page 191

1 A. Correct.

2 Q. So did you do that with the McGovern
3 paper?

4 A. Yes.

5 Q. Okay. Well, did you -- in considering the
6 McGovern paper, did you look at the specific pattern
7 of infections?

8 A. I'm not sure what you mean by "pattern."

9 Q. Well, the -- okay. Did you -- when you
10 were looking critically in evaluating all the data,
11 did you look at the individual infection types that
12 were occurring during the study, the two arms of the
13 study period?

14 A. When you mean infection types, you mean
15 the pathogens?

16 Q. The pathogens, the bugs.

17 A. I certainly looked at that, yeah.

18 Q. And how did -- well, what -- what did you
19 look at to -- to assess that?

20 A. You mean specifically what did I look at?

21 Q. Right. Are you talking about just what
22 was printed in the study, or did you look at
23 anything else?

24 A. I looked at a line list that I believe was
25 one of the exhibits.

Page 192

1 MR. C. GORDON: See if this helps.
2 (Exhibit 18 marked.)

3 BY MR. C. GORDON:

4 Q. I'll show you what's been marked as
5 Exhibit Jarvis 18. Previously marked as McGovern
6 Exhibit 16.

7 A. Yeah, that looks like it.

8 Q. So you reviewed this in your -- looking
9 critically in evaluating all the data of the
10 McGovern study; is that right?

11 A. Right.

12 Q. Did you -- let's focus on Staph aureus,
13 both methicillin susceptible and methicillin
14 resistant.

15 Did you look at the number of Staph aureus
16 cases that occurred during the Bair Hugger-only
17 period and compare that to the number of Staph
18 aureus cases that occurred during the HotDog-only
19 period?

20 A. Yes.

21 Q. And what did you find?

22 A. First of all, I found that my eyes are not
23 good and I needed a --

24 Q. Copy that.

25 A. -- magnifier for this thing. That was the

Page 193

1 first thing I learned.

2 Second I learned that it's hard to read
3 and there's duplication of information in it. And I
4 believe that -- I'm trying to see the -- I had them
5 lined up so it made it easier to see. But I guess
6 over here is -- that during the HotDog period, there
7 were infections caused by Staph epidermidis,
8 Enterococcus but none by Staph aureus.

9 Q. And during the HotDog -- strike that.

10 So during the HotDog period there was zero
11 Staph aureus infections; correct?

12 A. There were only three infections but,
13 yeah, none were Staph aureus.

14 Q. And you read Dr. Reed's testimony where he
15 said there should have been an additional infection
16 in the HotDog --

17 A. Right.

18 Q. -- arm, correct?

19 A. Right. I don't know what the pathogen was
20 with that one. It might have been Staph aureus; I
21 don't know.

22 Q. And in the Bair Hugger-only period, how
23 many Staph aureus infections were there?

24 A. I don't know that I counted them.

25 MR. B. GORDON: Just for the record while

Page 194

1 he's counting or looking at, object to all of this
2 as -- I don't know if this has been authenticated,
3 Corey, but all this data as being of uncertain
4 veracity. I don't know anything about where it came
5 from. Has this been authenticated by anyone?

6 MR. C. GORDON: It was produced by
7 Dr. McGovern.

8 MR. B. GORDON: All right. Well, I just
9 want to object for the record.

10 THE WITNESS: I believe 19. But I could
11 have counted wrong.

12 BY MR. C. GORDON:

13 Q. Well, in terms of the total number of
14 infections attributed to the Bair Hugger-only
15 period, whether it's 19 or 18 or 20, would you agree
16 that the Staph aureus constituted the majority of
17 infections in the Bair Hugger-only period?

18 A. I think so. Yes. There's a lot of
19 coagulase negative Staph as well.

20 (Reporter asks for repetition.)

21 Coagulase negative Staphylococcus.

22 MR. B. GORDON: And again I want to object
23 for the record to the extent we don't know if this
24 is the final data or not which could change the
25 results.

Page 195

1 BY MR. C. GORDON:

2 Q. And focusing for a moment just on the
3 Staph aureus where the majority of the Bair
4 Hugger-only and none of the HotDog-only, are you
5 aware of any interventions that occurred at
6 Northumbria during the Bair Hugger period or prior
7 to or during the HotDog period that would have
8 preferentially had an impact on Staph aureus?

9 A. Well, I'm aware that they began a -- what
10 they call, I think, an MSSA screening protocol
11 which, you know, one could argue might have an
12 impact. First of all, they talk about the
13 screening, but they don't talk much about what they
14 did with the screening. But let's assume they did
15 some kind of decolonization.

16 Q. Did you read Dr. Reed's testimony about
17 what they did when there was a positive MSSA screen?

18 A. I'm trying to remember if I did or not.

19 Q. Well --

20 A. I think they -- I think he may have
21 mentioned using mupirocin.

22 (Reporter asks for repetition.)

23 Mupirocin. M-U-P-I-R-O-C-I-N.

24 And I can't remember about chlorhexidine.

25 But even given that, Dr. Wenzel did a

Page 196

1 randomized control trial and showed that it didn't
2 have any significant impact on MSSA.

3 Q. Do you advocate MSSA screening for joint
4 arthroplasty?

5 A. Certainly if I were having a joint
6 procedure I would request it. Is it a consensus
7 among orthopedic surgeons or infectious disease
8 colleagues? No.

9 Q. They went to a chlorhexidine skin prep too
10 at some point; correct.

11 A. Correct.

12 Q. Did they -- were there any additional
13 Staph aureus infections after they switched to the
14 chlorhexidine prep?

15 A. I would have to look back to see what the
16 date was of when they changed that.

17 Q. I guess my bigger question is did you do
18 that? Did you correlate the dates with the changes?

19 A. I probably did write it down somewhere.

20 Q. Well, you know, your counsel gave me --
21 this morning gave me copies of some notes. Let's go
22 ahead and mark those and see -- if they're in there,
23 great; if not, then not.

24 (Exhibits 19 - 20
25 marked.)

Page 197

1 BY MR. C. GORDON:

2 Q. Showing you Exhibits 19 and 20. What are
3 these documents?

4 A. 19 looks like it's copies of my notes from
5 the various depositions.

6 And 20 is kind of a compilation of things.
7 So it includes listing of a variety of different
8 issues such as contaminated Bair Hugger units in the
9 1, 2, 3, 4, 5, 6 studies that document that. The
10 increase in particles in the sterile field with Bair
11 Hugger in the 1, 2, 3, 4, 5, 6 studies documenting
12 that. The impact of the Bair Hugger on disruption
13 of laminar flow on 2, 3, 4 studies documenting that.

14 A few notes from clinical director
15 Van Buren [sic] from 3M talking about the growing
16 concern about infection potential of the Bair
17 Hugger. And that he acknowledges decreased
18 particulates would lead to decreased SSI risk.

19 And then a comment from an e-mail, I
20 believe it was, from -- I'm not sure how you
21 pronounce her name Hulse-Stevens or Sterums
22 [phonetic] or something.

23 (Reporter asks for repetition.)

24 H-U-L-S-E, dash, S-T-E-V-E-N-S.

25 Where she went to an international

Page 198

1 consensus conference I think of orthopedic surgeons
2 and said there's energy around the issue of
3 prevention of prosthetic joint infections. And the
4 possibility that forced air warmers increased
5 particulates and increase infection.

6 So there was a section on Project Ducky
7 where they were looking at trying to incorporate
8 HEPA filtration into the Bair Hugger but ultimately
9 didn't do it.

10 Q. Let me interrupt you here because I'm a
11 little confused. Your notes are quoting from things
12 that I don't think on your -- either your reference
13 list or your "Additional Materials Reviewed" list.
14 Were you looking at a document about Project Ducky
15 or looking --

16 A. I think these -- I think Project Ducky was
17 part of a -- I'd have to go back and look, but I
18 believe it was Van Duren or Hansen or one of the
19 depositions.

20 Q. Okay. I don't see -- Van Duren's not on
21 your list of the depositions you reviewed. So
22 that's another question I'm curious about. But --

23 A. I'd have to look.

24 Q. Where --

25 A. It was definitely a 3M e-mail that I

Page 199

1 believe was -- I think it was an exhibit on one of
2 the depositions.

3 Q. Okay.

4 A. Van Buren may have -- I'd have to look.

5 Q. Can you tell when these notes were
6 written?

7 A. No. I've not dated them.

8 Q. But do -- do either or both of those
9 pre-date your report?

10 A. This -- some do, some don't.

11 Q. Can you tell --

12 A. So, for instance, this first page on
13 Exhibit 20 is after my report. But the bottom part
14 there, the 3M e-mails was before the report. Not
15 written -- this part was not written but this was
16 stuff that I already knew. Same with Project Ducky.
17 And then the kind of the bottom two-thirds of that
18 back of the first page is from after the report.

19 Q. The third page of the -- Exhibit 20, the
20 top reference there is to Julie Gillson, October 14
21 article. Is that something you had read prior to
22 your report?

23 A. No. No, that's after.

24 Q. So prior to your report, did you have
25 any -- writing your report, did you have any

Page 200

1 information about the various infection control
2 practices that had been implemented at Northumbria
3 during or prior to the -- well, at any time during
4 the Bair Hugger/HotDog observational study?

5 A. I'd say if they were mentioned -- and I
6 don't remember specifically if they were mentioned
7 in the -- either the Reed or the Albrecht
8 depositions.

9 Q. Do you recall if you learned anything
10 after the report about infection control practices
11 that were implemented that you -- that was new to
12 you that you thought, oh, gee, I didn't know they
13 did that.

14 A. I'm trying to think. You know, the other
15 exhibit that I think was either Reed -- I'm not sure
16 when that was. The graphic. I had seen that. But
17 I can't remember if that was before the report or
18 after.

19 Q. Oh. The chart?

20 A. Yeah.

21 Q. In Gillson?

22 A. Yeah, yeah. Because I think Gillson was
23 like October, publication date.

24 (Reporter asks for repetition.)

25 Gillson was published in October.

Page 201

1 Q. Regardless of source, I'm just -- what I'm
2 really trying to understand is if after you wrote
3 your report you saw anything or heard anything that
4 made you go oh, I guess I didn't realize they had
5 done X at Northumbria.

6 A. Not that I recall.

7 Q. Now going back to your definition -- the
8 concept of an outbreak. Can you recall reading in
9 Dr. Reed's deposition that the National Health
10 Service in England had identified Northumbria as
11 being a high outlier for its orthopedic infection
12 rates?

13 A. I remember him talking about them getting
14 some communication from -- I guess it's Health --
15 HPA. Health Protection Agency. Changed its name
16 now to something else. And him commenting that to
17 some extent that probably depended a bit on the
18 surveillance done by different trusts and that some
19 trusts -- at that point they only had to do
20 surveillance for -- I think there were four
21 procedures that you had to do; three months of
22 surveillance for an entire year. So different
23 people were doing surveillance for different
24 procedures. The intensity of surveillance was
25 different and we know that if you're not doing

Page 202

1 post-discharge surveillance or comprehensive reviews
2 really of the records, you're probably
3 underreporting your rate. And that his feeling was
4 that there probably was underreporting by other
5 hospitals. And that was kind of part of the reason
6 why their rate might look higher than others.

7 Q. Your -- when you did the -- your
8 evaluation of all the data and you saw that there
9 were 19, give or take, Staph aureus infections
10 during the Bair Hugger period, did that strike you
11 as a potential outbreak issue? That they had a
12 problem with Staph aureus?

13 MR. B. GORDON: Object to the form.
14 Assumes facts not in evidence.

15 THE WITNESS: Yeah, I don't know that I
16 thought it was an outbreak issue because there's
17 certainly -- you've got a group at the very top at
18 the beginning that are kind of one after another,
19 but then the others are kind of scattered around.
20 So -- and -- and certainly in his deposition he
21 didn't acknowledge any specific outbreak that was --
22 that was occurring. And obviously Staph aureus,
23 coagulase negative Staphylococci are the number one
24 and two most common organisms to cause prosthetic
25 joint infections. So you wouldn't expect that there

Page 204

1 good epidemiologic investigation almost always
2 identifies the source. And then the laboratory
3 either cultures and/or typing confirms that.

4 BY MR. C. GORDON:

5 Q. And when you do a good epidemiological
6 survey, specifically looking at joint infections,
7 you want to consider every possible factor; right?

8 MR. B. GORDON: Object to the form.

9 THE WITNESS: Well, I guess it depends on
10 what you mean by consider. Certainly one of the
11 things we always did for our outbreak investigations
12 and one of the things I think you would want to do
13 is to look at the literature. If you have a cluster
14 of, say, Pseudomonas infections, you know, what has
15 been described in the past as being the cause of
16 such infections? And make sure you look at those
17 things and exclude those things. Obviously those
18 are the most likely sources. And unlikely sources
19 might still be a possibility and you should evaluate
20 them.

21 MR. C. GORDON: Well, let me show you
22 Exhibit 21.

23 (Exhibit 21 marked.)

24 BY MR. C. GORDON:

25 Q. This is a paper you co-authored; correct?

Page 203

1 would be a list of you know, Aspergillus; and
2 Burkholderia, and Acinetobacter, and a lot of other
3 organisms. And really the only way to know would be
4 to do genetic typing of those organisms.

5 BY MR. C. GORDON:

6 Q. That's the only way you can link up a
7 specific --

8 A. That's one way --

9 Q. Let me finish the question.

10 -- a specific infection and a specific
11 source; right?

12 MR. B. GORDON: Object to the form and
13 beyond the scope of this deposition.

14 THE WITNESS: That is one of the ways.
15 One of the messages from the outbreak investigations
16 that we did was that epidemiologic methods really
17 trump laboratory methods. And that's why we've
18 always recommended not doing just culture surveys.
19 A lot of times a cluster will occur and what I
20 describe in my report and in these papers is, quick
21 and dirty is, for infection control people just to
22 go around and start culturing all sorts of stuff and
23 send it to the laboratory. It's relatively easy for
24 them to do. Puts the burden on the laboratory. And
25 usually doesn't identify the source. So doing a

Page 205

1 A. Correct.

2 Q. And in this case you are -- you
3 conducted -- you and your colleagues conducted an
4 investigation into outbreak of wound infections in
5 knee arthroplasty; right?

6 A. Correct.

7 Q. You looked at two hospitals; right?

8 A. Correct.

9 Q. You -- in the time period you looked at,
10 there were 20 infections that you identified; right?
11 A little under --

12 A. Correct.

13 Q. -- not quite four years. '84, '85, '86,
14 and almost all '87; right?

15 A. Until November '87; right.

16 Q. And of those 19 -- of those 20 infections,
17 18 of them were deep joint infections; right?

18 A. I'm trying to see where it says that.

19 Yes. Yes. Okay.

20 Q. And do you know what the -- so can you --
21 it's not in here. I had to calculate it myself.
22 But can you tell us what the deep joint infection
23 rate was for knee arthroplasty in the study that you
24 did?

25 A. During the epidemic period or during the

Page 206

1 pre-epidemic period?

2 Q. During the -- the epidemic period, is that
3 January 1, '84 to '87?

4 A. January 1, '84 to November 30, '87.

5 Q. Yes. During that period.

6 A. 7.7 percent.

7 Q. That was -- that included the two SSI --
8 superficial SSIs; correct?

9 A. Correct.

10 Q. So my question was can you calculate
11 knowing that 18 of those were deep joint infections,
12 what the actual deep joint infection rate was?

13 A. Well, if the question is can I calculate?
14 The answer is yes.

15 Q. Is it about 5.8? Does that sound about
16 right?

17 A. (Witness pulls out calculator.)

18 Q. Ah, Smartphones.

19 A. 6.9.

20 Q. So that was -- and that was just for
21 knees; right?

22 A. Correct.

23 Q. And, in fact, you note that -- on page 906
24 that there were -- there was no increase in the
25 infection rate for patients undergoing hip

Page 207

1 replacement at these two hospitals; right? Is that
2 right? Sorry.

3 A. Right.

4 Q. And so the -- would that be the type of
5 situation that would result in an outbreak
6 investigation? You've got an unusually high number
7 of joint infections with knees but not with hips?

8 A. Correct.

9 Q. In the McGovern paper, did you notice the
10 ratio of hip infections to knee infections?

11 A. Yes.

12 Q. Do you recall what it was?

13 A. I'd have to look. I think knee was higher
14 than hip.

15 Q. You think knee was higher than hip?

16 A. I would have to look. But it was the
17 opposite of what you said.

18 Q. Okay. Well, whatever it is, it was the
19 opposite of what you would expect. Is that what you
20 recall?

21 A. What's commonly found, yeah, yeah.

22 Q. And was it -- when you say "opposite," was
23 it just a little bit off or was it -- was it a
24 pretty big difference?

25 MR. B. GORDON: He already said he'd need

Page 208

1 to look at the study to know for sure.

2 MR. C. GORDON: That's fine.

3 THE WITNESS: Sorry about that.

4 So 4.6 percent on hip; and 1.7 percent in
5 knees.

6 BY MR. C. GORDON:

7 Q. Well, I'm looking at the bottom of page
8 1542 and where they say, "It was, however, somewhat
9 unusual that the odds of infection associated with
10 hip replacement were 4.1 times greater than the odds
11 for knee replacement. Typically infection rates are
12 greater for knee replacement."

13 Do you see that?

14 A. Correct.

15 Q. So instead of being slightly more knees,
16 it was more than four times as many hips in this
17 particular study; right?

18 A. Yes.

19 Q. And when you did your -- when you look
20 critically and evaluated all the data, what -- what
21 did you -- how did you factor in this anomaly that
22 there were 4.1 as many -- that the odds for
23 infections in hips were 4.1 times that of knees?

24 MR. B. GORDON: Object to the form,
25 counsel's characterization.

Page 209

1 THE WITNESS: I would say that I just --
2 you know, that's what happens when you do a study in
3 a real-life situation rather than a control
4 situation. You may find things that are slightly
5 different than have previously been described.

6 BY MR. C. GORDON:

7 Q. Well, in the paper you did in 1990,
8 Exhibit 21, the signal that caused the concern was
9 that the knee rates were substantially higher than
10 the hip rates; right?

11 A. Well, I think as much as anything, it was
12 that the rate in knees was so high and that it was
13 clustered around one individual surgeon.

14 Q. Well, you didn't know that going in;
15 right?

16 A. Well, to some extent we did. Brian
17 Simmons is actually the hospital epidemiologist who
18 was at that hospital and he had been doing
19 surveillance and actually had an idea that that was
20 what was going on and felt that he would be able to
21 deal with the surgeon, if you will, if CDC came in
22 and confirmed what he initially had found and helped
23 him.

24 Q. So he had a surgeon that he suspected was
25 a problem?

Page 210

1 A. Correct.

2 Q. Was this surgeon doing both hips and

3 knees, or was he only -- he or she only doing knees?

4 A. I don't remember.

5 Q. Do you have any reason to -- strike that.

6 Do orthopedists who do implant surgery

7 always do both hips and knees? Or are you aware of

8 some who do predominantly one versus the other?

9 A. I've never seen a survey of orthopedic

10 surgeons to answer that. My guess is some -- some

11 do both and some prefer doing one or some prefer

12 doing the other.

13 Q. To sort of cut to the chase on your study

14 in Exhibit 21, the -- one of the two factors you

15 identified as being strongly associated with the

16 abnormal increase in knee infections was this one

17 surgeon; right?

18 A. Correct. And his rate was literally 9

19 times, almost 10 times any other surgeon. So he

20 really stuck out. It wasn't a 4 to 1. It's 2 and a

21 half times that. And this is not just one surgeon.

22 Q. How many surgeons are involved in the

23 McGovern study?

24 A. I'm not sure. I thought I saw either --

25 one of the depositions I thought he said it was like

Page 212

1 certainly haven't described it in the paper.

2 Q. Or in any deposition testimony that you're

3 aware of?

4 A. Not that I recall, no. I don't remember

5 them being asked that either.

6 Q. Okay. And based on your study as well as

7 others, the surgical skill of a given surgeon can

8 have a huge impact on the joint infections; right?

9 MR. B. GORDON: Object to form. Lack of

10 foundation.

11 THE WITNESS: Well, surgical skill is

12 obviously very important. You hope that the

13 surgeon-specific infection rates are clustered very

14 closely in terms of rate and not like this where you

15 have one at literally 10 times the rate of the

16 others.

17 BY MR. C. GORDON:

18 Q. So I think it was 9 times. So 9 times the

19 rate is -- is -- that's -- that's a serious issue.

20 But 4 times the rate would not be in your mind?

21 A. Well, it's 9.4.

22 MR. B. GORDON: Objection to form.

23 BY MR. C. GORDON:

24 Q. Okay. So 10 times --

25 A. They say it's 2 and a half times 4, but --

Page 211

1 four or five surgeons, but I'd have to go back and

2 look at that.

3 Q. Okay. And did all of the surgeons do

4 roughly an equivalent number of hips and knees or --

5 A. I don't -- that certainly wasn't in the

6 paper.

7 Q. So whether there was one surgeon who was

8 doing a whole lot more hips than other surgeons you

9 don't have any knowledge one way or the other?

10 A. No. And certainly I would assume they

11 looked at -- you know, one of the things you would

12 look at in, you know, doing an analysis of surgeons

13 look at surgeon-specific --

14 (Reporter asks for repetition.)

15 Look at surgeon. Look at surgeon-specific

16 infection rates. I don't see that reported here.

17 But they may have looked at that.

18 Q. Well, you say you assume that. Do you

19 have -- as you sit here today, do you have any basis

20 whatsoever to testify either that they did or did

21 not give any consideration to surgeon-specific

22 rates?

23 A. Well, I don't know what they gave

24 consideration to. I think it would be something you

25 would look at and a surgeon would look at. But they

Page 213

1 Q. But if somebody -- when you were at the

2 CDC and somebody called and said, you know, boy,

3 we've got four times as many hips getting infected

4 as we do knees, you would have said well, that

5 doesn't mean anything?

6 MR. B. GORDON: Object to form.

7 THE WITNESS: Oh, no. We would give them

8 advice on what to look at. And one of the things

9 would be surgeon-specific infection rates. Many

10 times that's done and that's not the cause; you

11 know, that's --

12 BY MR. C. GORDON:

13 Q. Okay. There are other things that you

14 tell them to look at; right?

15 A. Well, absolutely.

16 Q. Let's take a look at your article on page

17 906. One of the things you did through your

18 comprehensive analysis to try to figure out what's

19 going on in this particular -- in those two

20 hospitals was you pulled the medical records and

21 reviewed those records on all the patients; right?

22 A. Well, not all the patients; all the study

23 patients.

24 Q. All the study patients, right.

25 And you looked at their age; right?

Page 214

1 A. Correct.
 2 Q. Their sex?
 3 A. Yes.
 4 Q. The etiology of the underlying joint
 5 disease?
 6 A. Yes.
 7 Q. Whether they had prior knee surgery?
 8 A. Yes.
 9 Q. The American Society of Anesthesiologists
 10 ASA classification of preoperative physical status?
 11 A. Yes.
 12 Q. Let me stop there for a second. What is
 13 the ASA classification of preoperative status?
 14 A. It's a core that anesthesiologists give
 15 patients that basically is kind of a health
 16 assessment. So if you have chronic disease, chronic
 17 lung disease, diabetes, peripheral vascular disease
 18 you're going to have a higher score than if you are
 19 a healthy 18-year-old.
 20 Q. Would that -- would that be one way of
 21 assessing a patient's fitness for surgery?
 22 A. Well, most patients also get a, you know,
 23 preoperative evaluation by an internist in terms of
 24 that. So if they had cardiac disease, somebody
 25 signs off saying they're fine, usually not the

Page 215

1 anesthesiologist during that. It's more a way to
 2 categorize patients.
 3 Some have used it or thought of it as kind
 4 of a severity of illness measurement. But it
 5 doesn't work very well for that because
 6 anesthesiologists probably for medical/legal reasons
 7 tend to upgrade patients to make them look like
 8 they're sicker. So if they dropped dead in the
 9 middle of surgery they can say yeah, look, their ASA
 10 score was 4; what do you expect?
 11 Q. So in your study, Exhibit 21, the -- in
 12 addition to the surgeon-specific factor, the other
 13 factor that you found was strongly associated with
 14 the increased risk was patients who had an ASA
 15 rating of 3 or higher; right?
 16 A. Correct.
 17 Q. And that -- that's -- you know that that's
 18 not unusual; that the correlation between ASA and
 19 joint infections, that's been replicated in lots of
 20 other studies; true -- correct?
 21 A. Well, certainly. The higher the ASA the
 22 more complications you might expect.
 23 MR. B. GORDON: I just -- I'm sorry to
 24 interrupt you, Corey, but I'll put a continuing
 25 objection on the record for this line of inquiry is

Page 216

1 going to case-specific diagnostic information. That
 2 is not the purpose of his report or this deposition.
 3 This is a general causation report and deposition.
 4 And I just want to make it clear that we're going to
 5 reserve our rights to the extent that you are using
 6 your time for case-specific causation issues.
 7 BY MR. C. GORDON:
 8 Q. Did the McGovern study consider any form
 9 of classification of preoperative physical status
 10 comparable to an ASA score?
 11 A. Well, I don't know what additional
 12 materials they might have abstracted or collected or
 13 analyzed. It's not a part of -- at least not
 14 reported in their Table 2 of the univariate factors.
 15 (Reporter asks for repetition.)
 16 Univariate. U-N-I-V-A-R-I-A-T-E.
 17 Q. Well, in fact in the McGovern paper, they
 18 say on page 1543, "We were unable to consider all
 19 factors that have been associated with SSI as the
 20 details of blood transfusion, obesity, incontinence,
 21 and fitness for surgery which have been identified
 22 elsewhere is important predictors for deep infection
 23 were not sufficiently detailed in the medical
 24 record."
 25 You see that?

Page 217

1 A. I'm trying to find that. 43?
 2 Q. 1543. First full paragraph -- In the
 3 middle of the first full paragraph there.
 4 A. Correct. You read that correctly.
 5 Q. So not only is there no indication that
 6 they did consider it, there's a -- there's a express
 7 indication that they did not consider patients
 8 specific factors?
 9 A. Or weren't able to get it, yeah. Right.
 10 Q. So in your -- but in your study, that was
 11 one of two significant factors that accounted for
 12 the infections; right?
 13 A. One of three factors.
 14 Q. The -- right. And we'll get to the third
 15 factor. But ultimately that you decided -- you
 16 concluded that that one by itself was not --
 17 well strike that. We'll come back. We'll talk
 18 about that.
 19 Going back to what else you looked at
 20 after the -- you looked at the results was
 21 preoperative hematocrit? Right?
 22 A. Correct.
 23 Q. And you looked at the use of steroids;
 24 right?
 25 A. Right.

Page 218

1 Q. You looked at the presence of diabetes;
2 right?

3 A. Right.

4 Q. You looked at the use of insulin; right?

5 A. Which would correlate with the diabetes,
6 yes.

7 Q. Right.

8 You looked at evidence of nosocomial
9 infection; right?

10 A. Right.

11 Q. You looked at the specific operating room;
12 right?

13 A. Right.

14 Q. You looked at the time of the day of the
15 operation; right?

16 A. Right.

17 Q. Why did you look at the time of day?

18 MR. B. GORDON: Again, I want a continuing
19 objection on all of this going to case-specific
20 inquiry concerning opinions about case-specific
21 causation.

22 Go ahead, Doctor.

23 THE WITNESS: Because in some outbreaks
24 that we've investigated, time of day ended up being
25 important. Particularly the first case of the day.

Page 219

1 Particularly if the first case of the day is on a
2 Monday after the operating room has been, quote,
3 closed down over the weekend. So it can lead to
4 issues related to the heating, ventilation, and
5 air-conditioning system and its functioning.

6 Also we had an outbreak where first cases
7 of the day were at increased risk because of
8 housekeeping when they were doing the cleaning of
9 the operating rooms at night, the anesthesiology
10 personnel had IV and other equipment set up for the
11 first case of the day. And the housekeeping people
12 were kind of whipping the mop around and getting
13 water and contaminating the devices before the
14 surgical procedure.

15 So basically our past experience in
16 investigating outbreaks we found a number of times
17 that time of day and even day of the week might be
18 important factors to look at. So we looked at them.

19 Q. Have you seen studies that have gone the
20 other way? You're -- the puzzled look you're seeing
21 is -- I thought the consensus was that you were
22 better off to have the surgery early in the day
23 rather than later after other procedures.

24 A. That's probably anecdotal. All I can say
25 is from the outbreaks that we investigated that

Page 220

1 those were a couple of things that we found.

2 Q. Okay. So you looked at the type of knee
3 pros- -- the knee prosthesis that was implanted;
4 right?

5 A. Right.

6 Q. And whether it was fixed with cement or
7 was cementless; right?

8 A. Correct.

9 Q. You looked at the number of personnel in
10 the operating room during the procedure; right?

11 A. Right.

12 Q. You looked at the presence of assisting
13 surgeons; right?

14 A. Right.

15 Q. You looked at whether there were
16 intraoperative irrigations; right?

17 A. Right.

18 Q. You looked at the duration of
19 post-operative wound drains; right?

20 A. Right.

21 Q. You looked at the use of antimicrobial
22 prophylaxis?

23 A. Right.

24 Q. You looked at whether -- at the timing of
25 the first dose of the antimicrobial prophylaxis

Page 221

1 relative to the skin incision; right?

2 A. Right.

3 Q. You looked at the total duration of the
4 operation; right?

5 A. Right.

6 Q. You looked at the total duration of the
7 use of the -- of the intraoperative limb tourniquet;
8 right?

9 A. Right.

10 Q. You looked at preoperative shaving; right?

11 A. Right.

12 Q. You looked at the -- the identity of the
13 surgeon; right?

14 A. Right.

15 Q. And you looked at the use of a continuous
16 passive motor machine. During post- -- excuse me --
17 including starting day and duration; right?

18 A. Right.

19 Q. That's something that was used after the
20 surgery was completed to get the patient -- to start
21 rehabbing; right?

22 A. Correct.

23 Q. You looked at the duration of
24 post-operative fever; right?

25 A. Right.

Page 222

1 Q. You looked at duration of antimicrobial
2 exposure or administration; right?

3 A. Correct.

4 Q. You looked at the -- the lag -- the time
5 between the surgery and when there was documentation
6 of a wound infection; right?

7 A. Correct.

8 Q. You looked at the wound culture results;
9 right?

10 A. Right.

11 Q. And you looked at the time of the total
12 knee arthroplasty procedure, the time period between
13 the -- the procedure and the first re-operation;
14 right?

15 A. Correct.

16 Q. Okay. You looked -- you gathered
17 information on all those factors as part of your --
18 your investigation here; right?

19 A. Right. And virtually all of those were
20 negative. And part of the reason for going in that
21 depth and looking at all of those factors was -- as
22 I said, Dr. Simmons had had a hunch of what was
23 going on. And we knew that if he were correct and
24 it end up being a surgeon-specific issue, that we'd
25 better have a lot of information on potential

Page 223

1 factors that that surgeon would then raise to say,
2 "Oh, no, it's not me."

3 So we looked at, as you can see, a very
4 wide variety of other factors, most of which ended
5 up being not significant.

6 Q. So are you saying you had no basis for
7 looking at those other factors?

8 MR. B. GORDON: Object to form.

9 THE WITNESS: No. I'm saying they are
10 factors that are potential. Many of them we
11 probably didn't need to look at. But they were to
12 make sure that when this surgeon objected, we could
13 point out all the things that we looked at that
14 weren't different.

15 BY MR. C. GORDON:

16 Q. Every one of those things that we just
17 went through that you looked at, there was at least
18 some basis for thinking that it could potentially
19 have an impact on the deep joint infection rate;
20 right?

21 A. Correct.

22 Q. I mean, you didn't look at the color of
23 the paint on the operating room walls; that wasn't a
24 factor you considered.

25 A. I don't think we looked at that; correct.

Page 224

1 Q. And you didn't -- you wouldn't have
2 considered that because there's no basis for
3 thinking that changing the color of the paint in an
4 operating room would have any impact on deep joint
5 infections; right?

6 A. Oh, I don't know. If Dr. Simmons had
7 said, you know, we've had a problem with the leak in
8 our operating room and we just had a -- you know,
9 painter come in and paint all the rooms then we
10 probably would have focused on that. But since
11 nobody said that, we didn't.

12 Q. Right. I'm talking about something as
13 innocuous as the change in color, not, you know,
14 painter leaving supplies or whatever might occur.
15 You didn't look at things that realistically
16 couldn't/wouldn't have had any potential to impact
17 the joint infection rates; right?

18 MR. B. GORDON: Object to form.

19 THE WITNESS: Well, we tried to focus our
20 attention on both, again, going back to the
21 literature, what the literature had said previously
22 were potential sources and other sources that we
23 thought in addition to that could be important.

24 BY MR. C. GORDON:

25 Q. Well, if the concern was the surgeon, you

Page 225

1 could have just looked at and compared that
2 surgeon's rate to the other surgeon's rates; right?

3 A. Oh, absolutely. Dr. Simmons had already
4 done that. But they don't [sic] think that was
5 going to be very convincing to the surgeon. And the
6 surgeon would have brought up the color of the paint
7 in the room and everything else you can think of.

8 Q. Well, certainly the surgeon would have
9 been interested in the ASA score, his patients
10 versus the other patients; right?

11 A. Probably, since most surgeons, that's one
12 of their arguments is I'm operating on sicker
13 patients than you are.

14 Q. And as it turned out, in this case that
15 was really true; wasn't it?

16 MR. B. GORDON: Object to the form.

17 THE WITNESS: Well, at least in terms of
18 ASA score greater/equal than 3.

19 BY MR. C. GORDON:

20 Q. Well, in terms of that surgeon's group of
21 patients versus the other surgeon's group of
22 patients, his patients were almost 4 times as likely
23 to have an ASA score of 3 or higher; right?

24 A. Right. But the potential confounding
25 variable there that I don't think we looked at was

Page 226

1 that he may have been linked with a specific
2 anesthesiologist who might score patients higher.
3 And I don't know that we looked at that.

4 Q. Is that something you considered looking
5 at at the time?

6 A. I -- what year is this? Nineteen --

7 MR. B. GORDON: Ninety.

8 THE WITNESS: 1990. I don't remember.
9 But that would be something that potentially we'd
10 look at.

11 BY MR. C. GORDON:

12 Q. Actually, in your paper don't you say that
13 the personnel in the operating rooms in the two
14 different hospitals were basically the same for the
15 other surgeons and they stayed in their own
16 hospitals. In other words, it was just the surgeon
17 moving back and forth?

18 A. Right.

19 Q. So if there was one anesthesiologist who
20 was scoring patients higher on their ASA ratings,
21 that wouldn't have differentially impacted one
22 surgeon going back and forth between the two
23 hospitals?

24 A. Well, he might have might have had a
25 favorite at both places.

Page 227

1 THE REPORTER: "Might have had"?

2 THE WITNESS: His favorite at both places.

3 BY MR. C. GORDON:

4 Q. Okay. So --

5 A. Just a possibility.

6 Q. But at least at the time you didn't
7 consider that either at all or any significant
8 enough possibility to actually investigate it?

9 A. Correct.

10 Q. But all these other things that you did
11 investigate -- and, by the way, you also spent
12 time -- some time to interview operating staff about
13 operating room procedures; right?

14 A. Correct.

15 Q. You took all this information and you did
16 a whole series of statistical analyses to see if any
17 one factor or any combination of factors could
18 explain the high rate -- the high rate of knee
19 infections during this period; right?

20 A. Right.

21 Q. And you used a series of multi-variable
22 analyses; right?

23 A. Right.

24 Q. And that's a way of comparing a -- several
25 different potential factors to see if one or more is

Page 228

1 having an impact on something; right?

2 A. That's one way of doing it; yes.

3 Q. Well, you could have done -- as I said,
4 when you were called in, you could have just looked
5 at surgeon X's infection rate and compared it to
6 everyone else and done a univariate analysis and
7 said it's all surgeon X; right?

8 A. Right.

9 Q. But by doing it this way you identified a
10 couple of other factors that were in play; right?

11 MR. B. GORDON: Object to form.

12 THE WITNESS: Right.

13 BY MR. C. GORDON:

14 Q. And one of those was the ASA score we've
15 talked about; right?

16 A. Right.

17 Q. And the other factor that you identified
18 was this passive motion thing; right?

19 A. The continuous motion.

20 Q. Continuous motion?

21 A. Passive motion.

22 Q. Continuous passive motion.

23 And the combination of those three factors
24 you concluded was -- of the problem or accounted for
25 the problem; right?

Page 229

1 A. Correct.

2 Q. So what would have -- well, strike that.

3 You couldn't reach -- you couldn't get to
4 that conclusion until you gathered all the
5 information about all these other potential factors;
6 right?

7 A. Well, you could have gotten that
8 information if you could have predicted the future
9 by just collecting data on those three factors and
10 be done. It would be a lot simpler.

11 Q. Right. But coming in after the fact and
12 trying to figure out why there was a higher -- why
13 there was a seemingly high rate of knee surgeries
14 going on at these two hospitals, even though you had
15 a working hypothesis that it was a surgeon-specific
16 issue, you looked at all these factors that you
17 reasonably thought could have had some impact on the
18 infection rates and you then did a whole series of
19 statistical analyses to flesh it out and see, you
20 know, is it live or is it Memorex; right?

21 MR. B. GORDON: Object to the form.

22 THE WITNESS: Well, certainly collected
23 all the data and did a variety of statistical
24 analyses on it, yes.

25 BY MR. C. GORDON:

Page 230

1 Q. And it wasn't just the surgeon; right?

2 A. Well, it mostly was the surgeon. The
3 surgeon was a problem. You take the surgeon away,
4 and the other -- the infections go away. So it's
5 the surgeon and the surgeon's technique that are
6 really the critical element here. Sure, his
7 patients might have been a little bit sicker than
8 other patients. Might have had more co-morbid
9 conditions. But the fact was he was the problem.

10 Q. Well, if he had -- if you had reduced his
11 patient load of patients with ASA scores of 3 or
12 higher by 75 percent, would he still have had that
13 high an infection rate, based on your -- the
14 analysis you did?

15 MR. B. GORDON: Objection --

16 THE WITNESS: Well, that's --

17 MR. B. GORDON: -- form; speculation.

18 THE WITNESS: Speculative that -- whether
19 he would have that high a rate. But my guess, given
20 what was going on, is he would have had a higher
21 rate than others operating on the same types of
22 patients.

23 BY MR. C. GORDON:

24 Q. You say on page 914 that before conclusion
25 could be drawn regarding surgeon X, it was essential

Page 231

1 to rule out the possibility that the combination of
2 these factors -- we've gone through many of them --
3 might account for the increased surgical wound
4 infection risk experienced by some of his patients;
5 right?

6 A. Where is that?

7 Q. 914. On the left-hand side of the first
8 paragraph of that page -- on that page. About 20
9 lines down.

10 A. Correct.

11 Q. And then you did a series of logistic
12 regression analyses; right?

13 A. Right.

14 Q. And that enabled you to conclude, "The
15 severity of illness and surgical technique were the
16 primary determinants for total knee
17 arthroplasty-associated wound infection"; right?

18 A. Right.

19 And, again, I think that -- you know,
20 certainly one of the things that was always done --
21 and it didn't matter if it was a surgeon, a nurse, a
22 circulating nurse, a scrub nurse, who it was in the
23 operating room -- if an epidemiologic study was
24 identifying an individual, we would go to the Nth
25 degree doing additional studies to really document

Page 232

1 and prove that that was the case. Because we knew
2 it potentially would have a devastating impact on
3 their career.

4 So the idea that we could come in and do
5 surgeon X versus everybody else -- infection? Yes,
6 no. Get a P value. Go to the hospital
7 administration and say, "Surgeon X is a problem,
8 fire him" -- we would never do. We would go to the
9 Nth degree looking at everything that could
10 potentially -- and even things that might not
11 potentially -- be associated with infection to make
12 sure we were as solid as possible.

13 And in this case there was also a large
14 number of patients who were having surgery done. So
15 the numbers are large enough that you can really do
16 a multivariate analysis or a stratified analysis.
17 Which you might not be able to do with smaller
18 numbers.

19 Q. But you don't think 3M is entitled to that
20 same consideration that the surgeon was; right?

21 MR. B. GORDON: Object to form.
22 Argumentative.

23 THE WITNESS: Well, I'm not aware that
24 there's a cluster like this at a hospital. If there
25 is and 3M wants to send me there, then I'll be happy

Page 233

1 to do exactly the same thing.

2 BY MR. C. GORDON:

3 Q. Let's go back to the McGovern paper. They
4 did a univariate analysis. The only two things
5 they -- the only factor that they considered in the
6 univariate analysis was whether it was Bair Hugger
7 or HotDog; right?

8 A. Well, they're doing a different type of
9 study. They're not doing a study of a specific
10 short-time outbreak investigation. And their
11 hypothesis from the very beginning of the study was
12 is the type of patient warming device associated
13 with increased risk of infection. So from the very
14 beginning they're doing a much more focused type of
15 study than we did in this outbreak investigation.

16 MR. C. GORDON: I'm sorry. Could you read
17 that back.

18 (Record read as follows:

19 "A. Well, they're doing a different
20 type of study. They're not doing a study of a
21 specific short-time outbreak investigation.
22 And their hypothesis from the very beginning of
23 the study was is the type of patient warming
24 device associated with increased risk of
25 infection. So from the very beginning they're

Page 234

1 doing a much more focused type of study than we
2 did in this outbreak investigation.")

3 BY MR. C. GORDON:

4 Q. I want to -- I'm sorry. There are several
5 parts of that, so I needed to have it heard back.

6 You said that they were -- "they" being
7 the McGovern group -- were not doing a specific
8 short-term outbreak investigation. Is that -- did I
9 hear that correctly?

10 A. They did not identify a -- cluster of
11 infections, was not what led them to go and do an
12 investigation like we had with outbreak in
13 Tennessee.

14 Q. What do you --

15 A. Tennessee was we have a large cluster of
16 infections. Why is that occurring?

17 Q. What -- I want to parse this apart. What
18 do you mean by "short-term"?

19 A. Well, here in outbreak, most --

20 Q. In your paper, you mean.

21 A. Right. Most outbreaks are occurring over
22 a relatively short period of time. They don't go on
23 for, you know, three years or even a year.

24 Q. Your period was 47 months; right?

25 A. Well, over a long period of time. That's

Page 235

1 not when all of those infections were occurring,
2 though.

3 Q. So when -- what was the period of time
4 that the infections were occurring?

5 A. I had cluster, but really it's over a --
6 about a year period of time. He was having them
7 virtually over a month. So it wasn't we have one,
8 you know, now and we have one then.

9 Q. Why didn't you just look at that one year
10 then?

11 A. Oh, we potentially could have. But again,
12 as I say, we were trying to be very -- very
13 conservative.

14 Q. Okay. Now in the McGovern paper you said
15 that the hypothesis was the patient warming device
16 was impacting infection rates; right?

17 A. Or is there any difference in infection
18 rates given two different types of warming devices?

19 Q. Wasn't the -- your hypothesis on the study
20 you did in Tennessee that one particular surgeon was
21 accounting for the -- the high rate of infections?

22 MR. B. GORDON: Objection. He didn't say
23 that.

24 THE WITNESS: Well, to begin the process
25 at that hospital in Tennessee was to show that the

Page 236

1 rate of infection was higher than the past rate. I
2 don't know that I've seen any -- certainly anything
3 reported in the McGovern paper that they had done
4 that kind of analysis. It really was kind of a
5 combination of change in use of a warming device
6 around the same time that the Health Protection
7 Authority mandated surveillance for prosthetic joint
8 infections in certain patient populations. So it
9 was kind of a combination of factors. But it was
10 not -- I don't recall them saying we had elevated
11 prosthetic joint infection rate, therefore we did
12 this study.

13 BY MR. C. GORDON:

14 Q. Is it your understanding that the switch
15 from HotDog to Bair Hugger -- from -- excuse me --
16 from Bair Hugger to HotDog in the McGovern paper
17 occurred around the time that the HPA started
18 mandating surveillance?

19 A. No. No. Beginning of the intensive
20 surveillances was when the Bair Hugger was being
21 used and that's the start of when -- that's kind of
22 when they said we started collectings our data, is
23 when the Health Protection Authority mandated going
24 from doing surveillance on one of four procedures
25 three months of the year to doing intensive

Page 237

1 surveillance on basically a continuous basis. And
2 that's when they hired the additional, I would call,
3 infection control personnel. They call them
4 surveillance personnel.

5 Q. When you went into the situation in
6 Tennessee as is reflected in Exhibit 21, you were
7 already aware that there had been a univariate
8 analysis done of surgeon X versus everyone else, and
9 that showed that surgeon X had a statistically
10 significant higher rate of infections than the other
11 surgeons; right?

12 A. Well, I don't remember if we had that or
13 not. I know Brian Simmons had done some
14 investigation before we got there and had a strong
15 concern that surgeon X was problematic.

16 Q. So your working hypothesis when you went
17 in there was that surgeon X was likely to be a
18 factor; right?

19 MR. B. GORDON: Objection to form.
20 Misstates his testimony.

21 THE WITNESS: Well, we went in with an
22 open mind to say okay, you have an increased rate of
23 infection. Let's see what the cause is.

24 BY MR. C. GORDON:

25 Q. So in the McGovern paper, are you saying

1 they didn't go in with an open mind?

2 MR. B. GORDON: Objection to form.
3 Mischaracterizes his testimony.

4 THE WITNESS: No, I'm not saying they
5 didn't go in with an open mind. I'm saying that our
6 impetus in the outbreak was that there was an
7 outbreak. There was an elevated rate of infection.
8 I -- theirs was a specific hypothesis. Does the
9 type of warmer that we're using in patients in the
10 operating room have different rates of infection.

11 BY MR. C. GORDON:

12 Q. Well, there were different rates of
13 infection in one time period versus another; right?

14 A. Correct.

15 Q. And their hypothesis was that the
16 difference was because they had switched warming
17 devices; right?

18 A. Well, they did that comparison. That's
19 what they ultimately did their comparison of.

20 Q. And they didn't consider any of the other
21 factors that you considered in your Tennessee study;
22 right?

23 MR. B. GORDON: Objection to form. Asked
24 and answered.

25 BY MR. C. GORDON:

1 Q. Not one.

2 A. Actually, I don't think that's true. They
3 did look at some patient demographics that they had
4 available to them and said there were no
5 differences.

6 Q. What demographics?

7 A. I think it was during the deposition that
8 they talked about it. I don't know that they talked
9 about it here. Let me see.

10 Yeah. "The demographics of the 1437
11 patients undergoing hip and knee replacement
12 revealed no significant difference between the two
13 types of warming for SSI risk factors for age, type
14 of surgery, diabetes, and length of preoperative
15 stay."

16 Q. Okay. Sorry. Age, type of surgery,
17 diabetes? What was the? Length --

18 A. Age, type of surgery, diabetes, and length
19 of preoperative stay.

20 Q. Okay. They didn't do anything akin to --
21 on ASA preoperative physical status evaluation;
22 right?

23 A. No. They said that wasn't available.

24 Q. Right. And when you did your study, that
25 was -- that was a major factor?

1 A. Well, it ended up being a statistically
2 significant factor. But if it hadn't been
3 available, we wouldn't have been able to do it.

4 Q. You said that their study was much more
5 focused; meaning, the McGovern study. What do you
6 mean it was much more focused?

7 A. Well, they were looking at -- at least my
8 understanding is they were looking at a -- trying to
9 answer a specific question. Is there a difference
10 in infection rate with two different patient warming
11 devices.

12 So they're asking a specific question and
13 collecting data to try to answer that question
14 rather than, well, we have an outbreak. We have an
15 increase in infection. Of all the different things
16 that can be causing that, what is causing it.

17 Q. So if they had looked at all these other
18 factors in both time periods and seen that, gee,
19 there actually was a difference in one or more of
20 these factors between the time period not just the
21 patient warming, that could have impacted the
22 conclusions they drew; right?

23 MR. B. GORDON: Object to form.

24 THE WITNESS: Well, you would certainly
25 have to look at what they find and see does it make

1 any sense. It might have been -- going back to your
2 color of the room. It might have been the color of
3 the room. The blue room is where the infections are
4 occurring. Well, it may not make any sense. So you
5 have to look at anything that you find that is
6 statistically significant.

7 BY MR. C. GORDON:

8 Q. But first you have to look; right?

9 A. If you have the data.

10 Q. Okay. And so when you say it's much more
11 focused, what you're really saying is it was set up
12 to only look at certain things; right?

13 MR. B. GORDON: Object to counsel's
14 characterization.

15 THE WITNESS: No, I'd say they had a
16 specific hypothesis that they were trying to answer
17 and they collected the data and analyzed it that
18 they thought was pertinent to that specific
19 question.

20 BY MR. C. GORDON:

21 Q. And you collected data that you thought
22 was pertinent to the Tennessee situation; right?

23 A. Well, I'd say we collected much more than
24 that. If that had not been an individual surgeon,
25 we would not have collected that much information.

Page 242

1 Q. So tell me what you would -- what you
2 would have eliminated if they had just called in and
3 said, "Hey, our knee rates seem off the charts here;
4 help us out." What you would you look at?

5 A. Well, it would be driven by a line
6 listing. It would be driven by the past literature
7 and what risk factors there were. Each
8 investigation is individualized to that specific
9 issue.

10 Q. Yeah, but --

11 A. But we would not have probably focused as
12 much depth on certain factors in this outbreak if it
13 had not been from the very beginning highly likely
14 that the surgeon was going to be the cause.

15 Q. So I'm -- but my question is if you -- if
16 the hospital had contacted the CDC and said, "Our
17 knee rates are way higher than our hip rates and
18 they're out of whack from what we understand to be
19 the background rate at other places too, could you
20 come and help us," what would you have looked at?

21 MR. B. GORDON: Objection; asked and
22 answered.

23 THE WITNESS: Yeah, it would -- it would
24 vary again depending upon the situation. But -- you
25 know, presence of diabetes versus use of insulin.

Page 243

1 You know, probably one of those would be -- diabetes
2 is probably fine. Which is what they did. They
3 didn't look at insulin. But probably don't need to.

4 MR. C. GORDON: Okay.

5 THE WITNESS: So the cause of the
6 underlying disease. Probably not important. So --
7 you know, evidence of nosocomial infections.

8 So there's a lot of things that we're
9 looking at that were overkill, but the reason that
10 they were done was because we knew the probable
11 outcome was going to be a very serious matter, that
12 we needed to make sure we covered the potential --
13 any and all potential confounding variables that
14 might exist.

15 MR. B. GORDON: Are we getting close to a
16 good time for a break?

17 MR. C. GORDON: Yeah. One more question.

18 Q. Do you think these lawsuits are very
19 serious matters?

20 MR. B. GORDON: Objection; argumentative.

21 You don't have to answer that.

22 THE WITNESS: Oh, absolutely.

23 MR. C. GORDON: We can take a break.

24 THE VIDEOGRAPHER: The time is 3:37 p.m.
25 and we are off the record.

Page 244

1 (Recess taken from 3:37 p.m. to 3:51 p.m.)

2 THE VIDEOGRAPHER: This marks the
3 beginning of Volume I, file 5 in the deposition of
4 Dr. William Jarvis. The time is 3:50 p.m. and we
5 are on the record.

6 BY MR. C. GORDON:

7 Q. Dr. Jarvis, several times today you made
8 reference to a heater-cooler unit and you discuss
9 that in your report, your expert report; correct?

10 A. Yes, sir.

11 MR. C. GORDON: And I show you Exhibit 22.
12 (Exhibit 22 marked.)

13 BY MR. C. GORDON:

14 Q. This is the Sommerstein June 2016 paper.
15 This is something you reference in your report;
16 correct?

17 A. Yes.

18 Q. And this discusses an investigation into
19 an outbreak investigation of an unusual or
20 relatively rare bacterium -- Mycobacterium chimaera?

21 A. Chimaera. Chimaera.

22 Q. Openly they link to contaminated
23 heater-cooler units; right?

24 A. Correct.

25 Q. And in your report you describe the Bair

Page 245

1 Hugger as being very, very similar to the
2 heater-cooler unit; right?

3 A. Well, I described the -- it was broader
4 than that. It was more that the heater-cooler is an
5 example of a medical device that's been used in
6 cardiac surgery for literally decades that everyone
7 had assumed was safe and initially two patients were
8 reported in the literature -- peer-reviewed
9 literature that had this Mycobacterium chimaera
10 infection after cardiac surgery and they were --
11 literally had their surgery two years apart.

12 And they're written up as a case report.
13 And I thought it was interesting that the --
14 basically the last line in the abstract was, "No
15 nosocomial source was found." And it's published.
16 And it really was Sommerstein and colleagues in
17 Switzerland who read that and decided to go back and
18 look at their microdata to see if they had any
19 cardiac surgery patients with mycobacterium chimaera
20 and found they did that led them to do this study.

21 And by doing this study, they did the type
22 of investigation that we have done at CDC, which
23 identified the heater-cooler as the most likely
24 source. And in culturing the device, as well as the
25 air exhausted from this device, found that it was

1 releasing mycobacterium chimaera.

2 Since then a wide variety of others,
3 including the United States and around the world,
4 have found additional cases. Investigations done at
5 the manufacturing plant of one of the manufacturers
6 of this device Sorin, found that they -- some of the
7 devices had intrinsic contamination at the time of
8 manufacture. Some of them were extrinsically
9 contaminated after manufacture. And that even
10 though this has water in it, which is obviously
11 different than the Bair Hugger, that it's really not
12 water that's being aerosolized, it's the exhaust,
13 air, similar to the contaminated exhaust air that's
14 released from the Bair Hugger that has led to
15 contamination of the sterile surgical field and
16 surgical site infections.

17 And, in fact, since then a wide variety of
18 other organisms have been reported to the Food and
19 Drug Administration. So it's not just mycobacterium
20 chimaera. And other manufacturers of the devices
21 have been implicated as well. So it's an example of
22 a medical device that everyone thought was safe for
23 decades that now we know is not safe.

24 Q. Move to strike as nonresponsive.

25 Doctor, did you or did you not say on page

1 functional operating room." Starting with the very
2 last sentence on the left-hand column. "The smoke
3 reached the ultraclean airflow."

4 A. Okay.

5 Q. Okay.

6 A. Yes.

7 Q. So they give two figures for their
8 calculated mean airflow: .23 meters per second and
9 0.15 meters per second. Do you see those?

10 A. I do.

11 Q. What's the mean airflow of the Bair
12 Hugger?

13 A. In its exhaust?

14 Q. Yes.

15 A. I don't know.

16 Q. Do you have any order of magnitude
17 comparison between the mean airflow velocity of the
18 Bair Hugger and -- strike that.

19 Do you have any -- you may not have a
20 quantitative -- strike that.

21 You may not have a -- it's late in the
22 day. Strike that.

23 You may not have a quantitative number for
24 the calculated mean airflow velocity but do you have
25 a qualitative opinion as to whether the mean airflow

1 23 of your expert report, quote, "The Bair Hugger
2 FAWs are very, very similar to the HCUs"?

3 A. Yes.

4 Q. You didn't just use one "very." You said
5 "very, very similar to the HCUs"?

6 A. Yes.

7 Q. You really wanted to emphasize that
8 similarity; right?

9 A. They're very, very similar; right.

10 Q. Let's take a look at the Sonner- --
11 Sommerstein paper, Exhibit 22. Page 1010 of that,
12 if you would. Starting at the bottom of the
13 paragraph on the left-hand side. It says, "The
14 smoke reached the ultraclean airflow 0.5 meters
15 beneath the ceiling outlet after 13 seconds, which
16 resulted in a calculated mean airflow velocity of
17 .23 meters per second. The smoke then reached the
18 surgical field 10 seconds later, which resulted in a
19 calculated mean velocity of 0.15 meters per
20 seconds."

21 Did I read that correctly?

22 A. I'm trying to find where you're reading.
23 It's on 1010?

24 Q. Yup. Under "Results."

25 "Smoke dispersal experiments in a

1 velocity of what comes out of the Bair Hugger is
2 anywhere near close to either of those figures
3 reported in Sommerstein?

4 A. No, I don't. But I don't think it's
5 really relevant. Because, as you can see, the Bair
6 Hugger is -- or excuse me -- the heater-cooler unit
7 is in the corner of the room way away from the
8 operating room; whereas, the Bair Hugger is usually
9 located right at the side of the anesthesiologist
10 near the operating room table. And I think 3M
11 acknowledges that the air from the Bair Hugger is
12 going into the blanket that's on top of the patient.

13 So we're talking about a device that's
14 releasing its air right next to the patient versus
15 one that's releasing air -- I don't care how fast or
16 how slow -- way across the room.

17 Q. So whether the mean airflow velocity of
18 the heater-cooler unit is sufficient to overcome the
19 downward force of the ultraclean airflow from the
20 ceiling, that, in your opinion, is irrelevant?

21 MR. B. GORDON: Objection. That's not
22 what he said.

23 THE WITNESS: Well, I'm not saying that.
24 It's obviously not irrelevant since patients are
25 getting infected. But what I'm trying to emphasize

Page 250

1 is that I think it's even a greater risk with the
2 Bair Hugger when it's releasing its contaminated
3 exhaust directly either onto the patient or under
4 the operating room table. If you move this device
5 right underneath the table, it would be even greater
6 danger than it already is.

7 BY MR. C. GORDON:

8 Q. In your report in several places you refer
9 to the contaminated exhaust from the Bair Hugger.
10 What's your evidence that the -- what comes out of
11 the Bair Hugger blanket is actually contaminated
12 with pathogens?

13 A. I think there's a number of studies that
14 have been done. We talked about some of them this
15 morning. But there's --

16 Q. Tell me what you contend supports your
17 opinion that actual viable pathogens are being
18 emitted from the Bair Hugger blanket?

19 A. Well, the studies that have been done I
20 obviously refer to in the paper, but -- or in the
21 report, but the studies documenting contamination of
22 the Bair Hugger unit include Baker, Bernardo,
23 Leaper. From 2009 Leaper; from 2001, Reed.

24 Q. Let me be precise with my question,
25 Doctor, because I know you want to go off and talk

Page 251

1 about particles. I'm not asking about particles.
2 I'm asking about viable bacteria. Do you have any
3 evidence, any study you can point to that shows
4 there are actual viable bacteria being emitted from
5 the blanket of the Bair Hugger when it is in
6 operation?

7 A. All of these studies that I'm referring to
8 here have documented contamination of either the air
9 coming in, the filter, past the filter, or the
10 exhaust of the Bair Hugger unit. And we know from
11 the Tsai study that soot can make it through that
12 blanket to the patient. And, if so, a number of
13 other studies have shown that bacteria, including
14 Staph aureus, can get through a .22 or a .45 micron
15 filter. And that the Bair Hugger blanket would not
16 be a sufficient secondary filter, if you will.

17 Q. Move to strike as nonresponsive.

18 Doctor, does any study that you have seen
19 demonstrate that actual bacteria have been measured
20 coming out of the Bair Hugger blanket?

21 MR. B. GORDON: Objection to Counsel's
22 tone and scowl.

23 He's answered the best he can.

24 THE WITNESS: Well, the majority of
25 studies that have been done have focused on the air

Page 252

1 coming out of the hose; documented that the air
2 coming out of the hose is contaminated.

3 BY MR. C. GORDON:

4 Q. Can you identify a single study that
5 showed bacteria coming out of the blanket; yes or
6 no?

7 MR. B. GORDON: Objection; asked and
8 answered.

9 THE WITNESS: I believe --

10 MR. B. GORDON: He doesn't have to answer
11 yes or no.

12 (Reporter asks for repetition.)

13 MR. B. GORDON: He doesn't have to answer
14 yes or no.

15 THE WITNESS: Most of the studies as I
16 mentioned have focused on the air coming out of the
17 hose which is --

18 BY MR. C. GORDON:

19 Q. I'm not asking you about --

20 A. -- contaminated --

21 MR. B. GORDON: Objection. You're
22 interrupting the witness.

23 BY MR. C. GORDON:

24 Q. I'm not asking you for most of the studies
25 and what they focused on. I'm asking you if there

Page 253

1 are any studies --

2 MR. B. GORDON: Corey --

3 BY MR. C. GORDON:

4 Q. -- anywhere that you're aware of that have
5 measured bacteria coming out of the Bair Hugger
6 blanket.

7 MR. B. GORDON: Corey, I know you're
8 getting excited, but you're going to let him finish
9 his answer.

10 MR. C. GORDON: No, at this point it's
11 filibuster.

12 MR. B. GORDON: And I object to
13 interrupting the witness. Let him finish.

14 THE WITNESS: No. As I said, they focused
15 primarily on the air coming out of the hose that has
16 been documented repeatedly to be contaminated. And
17 the Tsai study shows that the blanket would not
18 serve as a secondary filter.

19 BY MR. C. GORDON:

20 Q. So you have no study that shows bacteria
21 coming out of the blanket itself?

22 MR. B. GORDON: Objection; asked and
23 answered.

24 BY MR. C. GORDON:

25 Q. Right?

Page 254

1 A. No. As I said, they've -- the studies
2 have focused on the intake, the machine, and the
3 hose, air coming out of it.

4 BY MR. C. GORDON:

5 Q. Have you seen any studies that have
6 actually focused on what was going coming out of the
7 blanket?

8 MR. B. GORDON: Has 3M done?

9 THE WITNESS: I believe there's only --
10 I'm thinking there's only one very small study that
11 used agar plates that attempted to look at that.

12 BY MR. C. GORDON:

13 Q. What did it find?

14 A. In that study -- as I say, it's a very
15 limited study and they didn't find any.

16 Q. Are you aware of any studies that have
17 attempted to find bacteria -- well, strike that.

18 In one of your answers there I think you
19 said that there have been -- words to the effect of
20 several studies that have shown contaminated air
21 coming out of the hose. Is that essentially what
22 you were saying?

23 A. Correct.

24 Q. What studies --

25 A. And in swabs of the hose as well.

Page 255

1 Q. I'm not asking about swabs. I'm talking
2 about what's airborne. Are you aware of any studies
3 that have shown airborne bacteria coming out of the
4 hose?

5 A. I believe there is.

6 Avidan.

7 (Reporter asks for repetition.)

8 Avidan, A-V-I-D-A-N, in their first
9 experiment looked at nine Bair Huggers and one
10 WarmTouch. Had the hose nozzle suspended 40
11 centimeters over agar plates. And three of the nine
12 were positive.

13 Q. When you say "positive," how many CFUs
14 were counted on the agar plates?

15 A. They were using agar plates. So I don't
16 know that they quantitated them.

17 So they say in experiment 1, "Results.
18 Microbes present in the airstream of warmers (Bair
19 Hugger) grew corynebacterium" --

20 (Reporter asks for repetition.)

21 C-O-R-Y-N-E-B-A-C-T-E-R-I-U-M.

22 Another they grew staphylococcus.

23 Xylosus, X-Y-L-O-S-U-S. And aspergillus
24 fumigatus. F-U-M-I-G-A-T-U-S.

25 And another they grew Cryptococcus,

Page 256

1 C-R-Y-P-T-O-C-O-C-C-U-S.

2 Albidus, A-L-B-I-D-U-S.

3 And Aspergillus fumigatus. And
4 staphylococcus xylosus.

5 Those were all from air streams, not from
6 the hose.

7 Q. How many CFUs?

8 A. They did not quantitate it.

9 Q. And you said it was 40 centimeters off the
10 agar plate?

11 A. Correct.

12 Q. That's about 16 inches; right?

13 A. Right. So a lot closer than the
14 heater-cooler unit would have been to the operating
15 room table.

16 Q. Right. The air in between the end of the
17 hose and the agar plate, that's 16 inches or so of
18 air. Was that sterile air?

19 A. No. The only thing they grew was
20 aspergillus fumigatus.

21 Q. So were they -- did they do anything to
22 determine whether what they were capturing on the
23 agar plates 16 inches below the end of the nozzle
24 was coming out of the nozzle as opposed to being
25 blown onto the agar plate entrained from the

Page 257

1 surrounding air in that 16 inches of space?

2 A. Nothing specifically, no.

3 Q. And that's the same study that you said
4 once they put the blanket on and they put agar
5 plates right under it, they got nothing; right?

6 A. Well, they -- in that case, in contrast to
7 doing nine Bair Huggers, they just did two
8 experiments. And the direct airstream was for five
9 minutes.

10 Q. And they got nothing; right?

11 A. In those two experiments.

12 Q. Okay. And those were --

13 A. And they don't say how long the device had
14 been on prior to the five minutes. And we know it
15 takes, at least by other studies, 15, 20 minutes
16 before it reached study state.

17 Q. And those two were two of the three that
18 had bacteria, agar plates 16 inches below the
19 airstream of the hose; right?

20 A. Correct.

21 Q. Are you aware of any studies that tried to
22 measure the air directly coming out of the hose as
23 opposed to having any kind of a gap in between?

24 A. No. I think the others did swabs, focused
25 on swabs and/or actually taking liquid culture media

Page 258

1 and putting that in the hose.

2 (Exhibit 23 marked.)

3 BY MR. C. GORDON:

4 Q. Let me show you what's been marked as
5 Exhibit 23. Previously marked as Augustine
6 Exhibit 8. Ask if you've ever seen this before.

7 A. Yes.

8 Q. When did you see it?

9 A. I couldn't tell you that. I don't
10 remember.

11 Q. It's not listed on your references or your
12 "Additional Materials Reviewed"; is it?

13 A. Yeah, I can't remember if I saw it as an
14 exhibit. I may have. I don't remember.

15 Q. Well, I want to make sure we're talking
16 about the same thing. There are several other
17 exhibits to Albrecht that have that same "Augustine
18 Biomedical & Design Research Report" thing at the
19 top. But I will represent to you that this
20 particular report was only marked as an exhibit in
21 the Augustine deposition. So --

22 A. So I may not have seen it.

23 Q. Okay.

24 A. I may have just seen this front page. It
25 looks very similar to something I have.

Page 260

1 BY MR. C. GORDON:

2 Q. Do you remember what Albrecht said in his
3 deposition about that?

4 A. As I recall, he said that they were
5 basically testing a variety of different methods to
6 basically see what would work.

7 Q. And they couldn't capture any bugs using
8 any of the methods; right?

9 MR. B. GORDON: Objection to counsel's
10 characterization.

11 THE WITNESS: Well, or the methods that
12 they used for the times that they -- you know,
13 duration of the times that they used it, they hadn't
14 detected it. But that they were just kind of just
15 -- it was more just experimentation trying to figure
16 out what method would be the best to try.

17 MR. C. GORDON: Let's go back to the HCUs.
18 (Exhibit 24 marked.)

19 BY MR. C. GORDON:

20 Q. Let me show you what's been marked
21 Exhibit 24. These are record of proceedings from
22 the HICPAC meeting December 1 through 2, 2016.

23 Have you seen this before today?

24 A. I believe I've seen sections. I think
25 I've been online or I've looked at parts of it.

Page 259

1 Q. Okay. So were you aware prior to this
2 moment that Augustine Biomedical had done some
3 experiments where they tried to capture any bacteria
4 that might have been coming out directly from the
5 air -- air hose?

6 MR. B. GORDON: Object --

7 BY MR. C. GORDON:

8 Q. -- the hose?

9 MR. B. GORDON: -- to the form. Lack of
10 foundation. I don't know if he's even had time to
11 even read this. If you want him to read the whole
12 thing, it's a 29-page document.

13 BY MR. C. GORDON:

14 Q. You don't have to read this. I'm just
15 asking you. As you sit here -- before you --
16 ignoring this. Did you have any knowledge that
17 Augustine Biomedical had done any internal testing
18 to try and capture bacteria that was coming out of
19 the very end of the Bair Hugger hose?

20 MR. B. GORDON: Objection to form. Lack
21 of foundation.

22 THE WITNESS: Yeah, I can't speak
23 specifically to Augustine. I kind of vaguely
24 remember that it might be Albrecht's deposition that
25 something was mentioned about that.

Page 261

1 Haven't read the whole thing.

2 Q. It's not listed in your references or your
3 "Additional Materials Considered [sic]"; is it?

4 A. I guess I would have included it as a CDC
5 update. But the date's different.

6 Q. Well, if you --

7 A. Basically I've gone to the FDA and CDC
8 websites repeatedly. And I go there to see if
9 they've updated things. I don't put it -- write
10 down every date that I go there.

11 Q. Well, do you recall -- but you don't
12 recall seeing the December 1 and 2, 2016 meeting
13 record?

14 A. I'd have to see what they say.

15 Q. Well, let's --

16 A. As I say, I might have read parts of this.
17 I certainly have not read all of this.

18 Q. Let's turn to page 46.

19 MR. ASSAAD: What exhibit is this?

20 MR. C. GORDON: 24.

21 MR. B. GORDON: What was 23?

22 MR. ASSAAD: What was it?

23 MR. C. GORDON: I think it --

24 MR. B. GORDON: Oh, yeah. Did you mark
25 that one 23?

Page 262

1 MR. C. GORDON: I think it was this one.
 2 MR. B. GORDON: Okay.
 3 BY MR. C. GORDON:
 4 Q. Have you made it to page 46 yet?
 5 A. Yes.
 6 Q. And there's a -- this is a -- essentially
 7 minutes of a presentation given by Dr. Michael Bell,
 8 the deputy director for the Division of Healthcare
 9 Quality Promotion, of the CDC; right?
 10 A. Correct.
 11 Q. Do you know Dr. Bell?
 12 A. I do.
 13 Q. In fact, it's Dr. Bell you've quoted in
 14 your report that -- words to the effect of nothing
 15 that blows air should be in an operating room;
 16 right?
 17 A. Correct.
 18 Q. And by -- you understood Dr. Bell to be
 19 referring to any piece of equipment that blows air.
 20 Is that -- that was your understanding?
 21 A. Correct.
 22 Q. So that would include computers that have
 23 little fans with CPUs in them; right?
 24 A. Well, he didn't give an exhaustive list of
 25 what he meant.

Page 264

1 oversight?
 2 A. I wouldn't agree with that.
 3 Q. Okay. So is it a -- as far as you know,
 4 is there a process within the CDC whereby for
 5 something to become an official position of the CDC
 6 there's some process that has to be undertaken?
 7 A. I'd say there's numerous processes. For
 8 instance, if you look at -- in a CDC publication,
 9 there's a very specific process that you go through
 10 to get clearance of a paper that you publish at CDC.
 11 And yet at the bottom of the paper there's usually a
 12 disclaimer that it doesn't repre- -- necessarily
 13 represent the views of CDC.
 14 Q. Okay. Is it your understanding as you sit
 15 here today that it's the official position of the
 16 Centers for Disease Control that no equipment that
 17 blows air should be in an operating room?
 18 A. Well, again, I can't speak for CDC. So
 19 I'd be speculating. Certainly Dr. Michael Bell has
 20 said that. And I presume Dr. Denise Cardo, that's
 21 his boss who would have reviewed this, agrees with
 22 that. I can't tell you how far up the chain of
 23 command it would have gone.
 24 Q. Well, let's see what Dr. Bell says in
 25 Exhibit 24, which you have in front of you.

Page 263

1 Q. Did he give any list?
 2 A. Well, he was talking about heater-cooler
 3 units. But he didn't -- no, he did not give an
 4 exhaustive list.
 5 Q. Dr. Bell doesn't speak for the CDC; does
 6 he?
 7 A. I don't know how you define that. He's
 8 deputy director of the division. So when he's
 9 speaking at a meeting like this, he certainly is
 10 speaking for CDC.
 11 Q. Okay. So if he says this is the way it
 12 is, that is a pronouncement -- an official
 13 pronouncement of the Centers for Disease Control; is
 14 that what you're saying?
 15 MR. B. GORDON: Objection to form.
 16 Argumentative.
 17 THE WITNESS: Well, I guess that you would
 18 have to ask the director of CDC that question
 19 because it probably varies by the director and who's
 20 saying it and what they're saying.
 21 BY MR. C. GORDON:
 22 Q. Well, in your experience does -- somebody
 23 who is a deputy director of a division, do they have
 24 the authority to speak as -- for the CDC? Without
 25 any vetting, without any review, without any

Page 265

1 Do you see where Dr. Bell at the very
 2 bottom of page 46 says that -- it says that Dr. Bell
 3 shared this draft device selection algorithm with
 4 HICPAC --
 5 A. Yes.
 6 Q. -- do you see that?
 7 Okay. And then on the next page there's a
 8 device selection algorithm. Don't worry. I'm not
 9 going to try and make you read that.
 10 A. Thank you.
 11 Q. But do you have any idea, first of all,
 12 what -- what the word "draft" means in this context?
 13 A. I'm assuming that it means that he's put
 14 this together and he's sharing it with HICPAC to get
 15 their comments and suggestions and it's not final
 16 yet.
 17 Q. That would be a normal process; wouldn't
 18 it?
 19 A. Well, it is a process, yes.
 20 Q. And the statement that you've quoted about
 21 "nothing that blows air should be in an operating
 22 room," that pre-dated this; didn't it?
 23 A. Yes.
 24 Q. And it was in the context of a HICPAC
 25 discussion about how to deal with the heater-cooler

Page 266

1 situation; right?

2 A. And Dr. Bell's assessment of other
3 equipment that has blowing air in the operating
4 room. I don't think he was being specific only to
5 heater-coolers or he would have said no
6 heater/cooler device should be in an operating room.

7 (Exhibit 25 marked.)

8 BY MR. C. GORDON:

9 Q. Okay. Well, I'm going to give -- show you
10 Exhibit 25. And I will represent to you that this
11 is a readable version of the device selection
12 algorithm that appears on page 47. And if you
13 follow that algorithm through, the algorithm starts
14 with a product X. And first question is, is it
15 reusable, yes or no.

16 Bair Huggers are reusable; right?

17 A. Correct.

18 Q. So you go over to the yes side. And then
19 is it used in a patient care area? High risk,
20 non-risk, or no-patient exposure.

21 We'll put the Bair Hugger in a high-risk
22 area; right?

23 A. I would.

24 Q. Okay. Then the next line down to the left
25 is "Is there" -- the box is "air/water interface."

Page 267

1 Do you see that?

2 A. Yes.

3 Q. Okay. And by the way, if you -- the text
4 on page 47 specifically says the high-risk box
5 includes consideration of the air/water interface
6 through processing issues," et cetera, et cetera.

7 Now, under "air/water interfaced" -- under
8 "air/water interface," the second box over from the
9 left is "uses fan"; right?

10 A. Correct.

11 Q. But under this algorithm you don't get to
12 whether it uses a fan or not unless there's an
13 air/water interface; correct?

14 MR. B. GORDON: Objection to counsel's
15 characterization of the document and his testimony
16 about what this means.

17 Also refer you to this paragraph for a
18 moment.

19 THE WITNESS: I'm sorry?

20 MR. B. GORDON: That's what he referred
21 you to there, the bottom of there.

22 THE WITNESS: Is there a question?

23 MR. C. GORDON: Yup.

24 Could you read it back, please.

25 (Record read as follows:

Page 268

1 "Q. But under this algorithm you don't
2 get to whether it uses a fan or not
3 unless there's an air/water interface;
4 correct?")

5 THE WITNESS: It actually looks like when
6 they're discussing it, that in fact that air/water
7 interface is merely being reinterpreted more as air
8 or water and not necessarily air/water interface.
9 And there's a considerable amount of discussion by
10 HICPAC members about adding a section regarding
11 whether a device can be cleaned at all, which we
12 know 3M has no recommendation for cleaning the hoses
13 of the device.

14 BY MR. C. GORDON:

15 Q. Can you show me where there's this
16 discussion where you contend it means -- shows that
17 the air/water interface means air or water?

18 MR. B. GORDON: I'm going to object. He
19 was in the middle of a sentence in explaining
20 exactly that. So let him finish.

21 MR. C. GORDON: I want to -- he can come
22 back and give a speech. I want to focus on the
23 air/water interface issue, not the cleaning issue.

24 MR. B. GORDON: He's answering the
25 question to the best of his ability in the context

Page 269

1 of this document and what you showed him.

2 BY MR. C. GORDON:

3 Q. Where in --

4 MR. B. GORDON: You interpreted it one
5 way. He's trying to give you his interpretation.

6 BY MR. C. GORDON:

7 Q. Right. Where in this document does it say
8 that air/water interface really means air or water?

9 MR. B. GORDON: I object to interrupting
10 the witness. Please let him finish his answer.

11 THE WITNESS: On page 47 at the bottom it
12 says, "High-risk box includes consideration of
13 air/water interface reprocessing issues and
14 instructions. Under the air/water interface are
15 items related to moisture, creates mist, uses fan,
16 requires water, uses tubing, dry-ability, biofilm,
17 resistance. These elements were included to
18 stimulate thinking. First-cut elements were
19 included to stimulate thinking about items that
20 impact reprocessing, as well as" -- blah, blah,
21 blah, blah, blah, blah, blah. And then they go on
22 to talk about the importance of cleaning devices.
23 "And the manufacturer should be providing better
24 instructions for cleaning devices."

25 BY MR. C. GORDON:

Page 270

1 Q. Is there --

2 A. It says, "Inclusion of air/water is
3 laudable. Air and water should receive attention
4 particularly after the experience with heater-cooler
5 units when their emissions were not taken into
6 account." That's page 48, fourth from the bottom
7 paragraph.

8 They also talk about maintenance is
9 important. Should be part of the criteria, which we
10 know. The hoses in the Bair Hugger cannot be
11 cleaned. There's no recommendation for that at all.
12 It says, "Consideration should be given to the
13 composition of the materials in the device such as
14 tubing links." We know that can be a problem.

15 Q. Doctor, I'll let you come back and talk
16 about cleaning all you want because I know that's
17 the big -- that you want to. But is there anything
18 else in here that talks about the air/water
19 interface? And I want to specifically focus on your
20 testimony from a few moments ago where you said you
21 read something that said it's air or water.

22 MR. B. GORDON: Object to the form. And
23 counsel's mischaracterizing his testimony; it's
24 argumentative. It says "air/water." You interpret
25 that one way. He's explained his interpretation.

Page 271

1 THE WITNESS: And they talk about --
2 Dr. Bell says, "The algorithm is a collection of
3 elements to be considered. Weighing a different
4 element needing to be taken into consideration is
5 likely to be challenging."

6 BY MR. C. GORDON:

7 Q. Is there anything in here that says that
8 when it says air/water interface what that really
9 means is air or water?

10 MR. B. GORDON: Object to the form.
11 Argumentative. It doesn't say "air and water." It
12 says "air/water."

13 THE WITNESS: (Witness reviews document.)

14 MR. B. GORDON: And it's asked and
15 answered. He's referred you to that sentence on
16 page 48.

17 THE WITNESS: Yeah, I would just say my
18 last answer is what I would say. If you look at
19 it -- he's asking for additional comments and
20 suggestions. And my interpretation of that is
21 air/water was could be air or water.

22 BY MR. C. GORDON:

23 Q. So you believe when they -- it says air
24 and water should receive attention," that really
25 means air or water?

Page 272

1 MR. B. GORDON: Object to form.
2 Argumentative.

3 THE WITNESS: Well, I think it means it
4 could be air and water or and/or water. And they're
5 talking about devices that need to be cleaned and
6 they're talking about devices that have hoses.

7 BY MR. C. GORDON:

8 Q. What does the word "interface" mean to
9 you?

10 A. Where two things interface.

11 Q. You have to have two things; right --

12 A. Right.

13 Q. -- not just one?

14 MR. B. GORDON: Objection to form.

15 THE WITNESS: It could be. That could be
16 one interpretation. Again this is a draft. And
17 he's asking for comments from other people in the
18 room.

19 BY MR. C. GORDON:

20 Q. What would an air interface be?

21 A. For instance, where the hose from the Bair
22 Hugger comes in contact with the blanket would be an
23 interface. And we know they're talking about
24 connections with hoses.

25 Q. I know. I'm talking about where it says

Page 273

1 "air/water interface." You're saying that your
2 interpretation of that is it means air or water
3 interface. I'm asking what's an air interface?

4 MR. B. GORDON: Objection to form.
5 Argumentative. Asked and answered.

6 THE WITNESS: Well, I -- and I just
7 described one for you.

8 BY MR. C. GORDON:

9 Q. And you think that's what Dr. Bell is
10 talking about and the HICPAC people are talking
11 about, that it's any -- any air interface with
12 anything I said?

13 MR. B. GORDON: Objection to form.
14 Characterization of the record. And argumentative.

15 THE WITNESS: Well, they're talking about
16 medical devices that are in the operating room.

17 THE REPORTER: They're talking about what?

18 THE WITNESS: Medical devices that are in
19 the operating room.

20 BY MR. C. GORDON:

21 Q. Actually, Doctor, they're talking about
22 devices where there's water and an interface with an
23 -- with the air in such a way that the bacteria that
24 could grow in the water could be aerosolized into
25 the air --

Page 274

1 MR. B. GORDON: Objection. Counsel's
2 testifying.

3 BY MR. C. GORDON:

4 Q. -- isn't it?

5 A. Well, that's one interpretation. That's
6 yours. I don't see where Dr. Bell specifically says
7 that, number one. And, number two, if it follows up
8 on his previous statement that no device blowing air
9 should be in the operating room, then obviously if
10 he limits it only to air/water interface, then he's
11 going to miss out on other potential dangerous
12 devices.

13 Also, if you think about it, he's
14 developed this or started the development of this
15 and hopefully it will lead to further discussion
16 because of the follow-up investigations that led to
17 the discovery of heater/cooler units being a
18 problem.

19 Obviously before that hadn't come up with
20 this. So hopefully this will be expanded to address
21 all of those other devices in the operating room
22 that have exhaust.

23 Q. How much do you charge per hour for your
24 expert work?

25 A. It varies depending on what I'm doing.

Page 276

1 Q. Do you charge those -- all those entities
2 the same thing?

3 A. Some more; some less.

4 Q. And what's your highest rate for
5 consulting?

6 A. For a one-hour presentation, it's -- I
7 think the highest I've charged is \$5,000 or \$7,500.

8 Q. Okay. And if you're doing some sort of
9 ongoing work as opposed to a single presentation, do
10 you go by the hour or by the project? Or how do you
11 do that?

12 A. It varies. I've done both.

13 Q. Do you have a standard hourly rate when
14 you're billing by the hour?

15 A. It's somewhat dependent upon what I'm
16 doing.

17 Q. Give me the parameters, ranges.

18 A. If I'm having to deal with media, it's
19 usually in the 8- or \$900 an hour range. If I'm
20 doing on-site outbreak investigation, it could be
21 somewhere in the 500 to \$700 an hour range.

22 Q. When was the last outbreak investigation
23 you did in the United States?

24 A. Well, I get asked to do them not
25 infrequently but I don't do them very often for the

Page 275

1 Q. Tell me the different rates.

2 A. For review and materials, it's \$700 an
3 hour. For sitting here with you it's \$800 an hour.
4 And at trial it's \$900 an hour.

5 Q. Is there a minimum fee for a deposition
6 too?

7 A. Yes.

8 Q. What's that?

9 A. I got to look. I think it's four or five
10 hours.

11 Q. And what percentage of your income in the
12 last couple of years has come from your work as an
13 expert witness in lawsuits?

14 A. I'd say probably 10, 15 percent.

15 Q. And what's the other 80 or 90 percent come
16 from?

17 A. My other consulting work that I do.

18 Q. Well, what kind of consulting work do you
19 do?

20 A. I consult in epidemiology, infectious
21 disease, hospital epidemiology and infection control
22 for medical device companies, for infection control
23 organizations, for ministries of health, for
24 hospitals or hospital systems, and occasionally for
25 individual practicing clinicians.

Page 277

1 very reason you're talking about. They're very
2 expensive.

3 Q. Who -- what type of organization asks you
4 in the United States?

5 A. Hospitals.

6 Q. Is there any reason those hospitals
7 couldn't go to the CDC and ask them to do
8 investigation?

9 A. Well, they could go to CDC. But, realize,
10 CDC is a -- first of all, it's a non-regulatory
11 agency except for NIOSH. Second is in order to have
12 CDC come and do an investigation takes a fair number
13 of approvals. It has to be approved at the branch
14 level. Then the division level. Then the center
15 level. And then the -- actually the group that
16 funds the people that go out and do the outbreak
17 have to approve it. It has to be approved by the
18 state health department.

19 So if there was an outbreak at
20 San Francisco General and they called CDC and said,
21 "We want you to come do an outbreak investigation."
22 If the San Francisco Health Department and the
23 California Health Department didn't concur with
24 that, they would not be allowed to go do it.

25 And in addition to all that bureaucracy,

Page 278

1 sometimes hospitals would like to keep it quiet.
2 And if they have their own private consultant do it,
3 they control the outcome. Whereas, if CDC comes,
4 it's available under the Freedom of Information Act.

5 Q. You're a board certified pediatrician;
6 correct?

7 A. Yes, sir.

8 Q. You are not board-certified in infectious
9 diseases; are you?

10 A. Board-eligible but I've never taken the
11 boards.

12 Q. Do you have board certification in
13 infectious diseases?

14 A. No.

15 Q. Are you -- do you consider yourself an
16 expert in orthopedic surgery?

17 A. In the actual performance of the surgery,
18 no.

19 Q. Do you consider yourself an expert in
20 computational fluid dynamics?

21 A. Definitely not.

22 Q. You described Dr. Elghobashi's CDC study
23 as excellent. Page 23 of your report. Do you see
24 that? Or do you recall that?

25 A. I don't recall it, but I can look and I

Page 279

1 think it's probably true. 23?

2 Q. Yup.

3 A. So "excellent study," yes.

4 Q. By what criteria did you come to the
5 conclusion that it was an excellent study?

6 A. By looking at the factors that he included
7 in it and basically the robustness of the study.
8 Certainly compared with Dr. -- I think it's --
9 Memarzadeh's letter to the editor.

10 Q. When did you read Memarzadeh's letter to
11 the editor?

12 A. I couldn't tell you. Certainly before I
13 wrote my report; that's for sure.

14 Q. Did you seek to obtain any information
15 about the underlying details of what Dr. Memarzadeh
16 did?

17 A. No, I figured if they were important, he
18 would have put them in the letter to the editor.

19 Q. Did -- well, when you say Dr. Memarzadeh
20 did something, it was actually the National
21 Institutes of Health that did it; wasn't it?

22 MR. B. GORDON: Object to counsel
23 testifying.

24 THE WITNESS: Well, that's like saying
25 Dr. Bell speaks for CDC. I don't know that even

Page 280

1 letters to the editor at NIH go through a review
2 process. It's certainly not peer-reviewed.

3 BY MR. C. GORDON:

4 Q. Okay. But in terms of who -- well, you
5 understand -- strike that.

6 You understand that Dr. Elghobashi did his
7 CFD at the request of plaintiffs' counsel in this
8 litigation; right?

9 A. Correct.

10 Q. And he was paid by plaintiffs' counsel in
11 this litigation for his CFD; right?

12 A. I would presume so.

13 Q. Whatever Dr. Memarzadeh said he did, that
14 was done through the National Institutes of Health;
15 right?

16 MR. B. GORDON: Object -- object;
17 counsel's misstating the facts.

18 THE WITNESS: Well, I have no idea if
19 someone asked him to do that or he did it on his own
20 or how it came about. I don't know -- he doesn't
21 say anything in his letter to the editor about that
22 so I don't know.

23 BY MR. C. GORDON:

24 Q. Did you ever -- you didn't ask plaintiff's
25 counsel to provide you with any documents they might

Page 281

1 have that would show you what Dr. Memarzadeh
2 actually did for his CFD, did you?

3 A. No. I figured if he had some information
4 and thought it was useful, he would have actually
5 written an actual peer-reviewed publication rather
6 than a letter to the editor.

7 Q. Did you -- you read Dr. Samet's report;
8 did you?

9 A. I did.

10 Q. You saw that he had cited in his list of
11 reference materials Memarzadeh documents that
12 actually were the whole CFD?

13 A. What was the last part?

14 Q. Did you see in Dr. Samet's report where
15 Dr. Samet had unpublished information about the
16 actual CFD modeling that Dr. Memarzadeh did?

17 A. I'd have to look back. I don't remember
18 that.

19 Q. Okay. Do you remember discussing the
20 Memarzadeh CFD with Dr. Samet when you met with him?

21 A. No.

22 Q. How did you determine that
23 Dr. Memarzadeh's CFD was not only not excellent as
24 Dr. Elghobashi's but was -- was unworthy of even
25 mentioning in your report?

Page 282

1 MR. B. GORDON: Object to the form.

2 Argumentative.

3 THE WITNESS: Because, as I said, it's not
4 a peer-reviewed publication. Letters -- as an
5 editor of a journal I can tell you letters to the
6 editor are not sent out for peer review. An editor
7 looks at it and decides, yeah, okay or no, not.

8 If Mr. Memarzedah thought it was an
9 important piece of work that he had done, I would
10 have expected him to write a full paper, not a
11 letter to the editor, that included his methods and
12 his results and his interpretation and submit it for
13 publication.

14 BY MR. C. GORDON:

15 Q. Was Dr. Elghobashi's study that you
16 describe as excellent peer-reviewed?

17 A. Not yet. But I don't know that he's not
18 writing it up for submission to publication. I have
19 no idea.

20 Q. So explain to me why you were able to --
21 why you thought Dr. Elghobashi's non-peer-reviewed
22 study commissioned by the plaintiffs was excellent,
23 but Dr. Memarzedah's CFD didn't even merit a mention
24 in your report?

25 MR. B. GORDON: Objection; asked and

Page 283

1 answered.

2 THE WITNESS: Well, because there's very
3 little in the way of methodology provided by
4 Dr. Memarzedah; whereas, Dr. Elghobashi has page
5 after page after page describing his methodology
6 what he's included, what he's not included, how he's
7 done it.

8 I have a much better understanding given
9 my limited understanding of that area of the extent
10 of work and the robust nature of his analysis,
11 compared to the very minimal description by
12 Dr. Memarzedah.

13 BY MR. C. GORDON:

14 Q. Have you ever seen a Bair Hugger in
15 operation?

16 A. Yes.

17 Q. When?

18 A. Well, I've probably seen it when I spent
19 time -- my -- part of my consulting work is going
20 into orthopedic surgical suites and providing
21 guidance on methods for reducing infections. So
22 I've seen it in those conditions. And I've seen it
23 outside the operating room as well.

24 Q. Have you specifically examined a Bair
25 Hugger in connection with this litigation?

Page 284

1 A. I don't know what you mean by specific.
2 I've not --

3 Q. Set it up.

4 A. -- taken a screwdriver and torn it apart,
5 no. But certainly in terms of turning it on, yes.

6 Q. Okay. When?

7 A. Within the last year. Not in the last
8 month. Within the last year.

9 Q. Where was -- where did you do that?

10 A. In Minnesota.

11 Q. In a law office or in a hospital or
12 somewhere else?

13 A. In an office. And actually they had it at
14 Science Day as well.

15 Q. Fair enough.

16 A. I think 3M gave a demonstration then.
17 Hopefully they knew what they were doing.

18 Q. Other than the demonstration that was done
19 at Science Day, did you -- have you seen -- have you
20 seen it set up and operating outside of an
21 incidental encounter in a hospital?

22 A. I'm not sure what you're getting at. I've
23 seen it in an operating room --

24 Q. I'm not saying --

25 A. -- and I've seen it in an office. I'm not

Page 285

1 sure what you mean. Have I seen it in a grocery
2 store? No.

3 Q. Now let's talk about the office. Where --
4 that was an office in Minnesota and separate from
5 Science Day? That's what I want to make sure.

6 A. Correct.

7 Q. And was that before or after Science Day?

8 A. Before.

9 Q. And how was it set up? Was it -- was
10 there a mock patient or a real patient? Was it --
11 was the -- blanket attached? Those sorts of things.

12 A. Blanket was attached. It was turned on.

13 Q. What type of blanket was it?

14 A. You mean what model number?

15 Q. Upper body. Lower body.

16 A. Upper body.

17 Q. Okay. And where was -- was there any
18 draping on it?

19 A. No.

20 Q. Was it pointed down or pointed up?

21 A. Down. In terms of air circulation, down.

22 Q. Right. Was it just on a table or on a
23 floor or -- where was it?

24 A. Both on a table and a floor.

25 Q. Okay. And what did you look at? What

Page 286

1 were you looking at?
 2 A. The whole thing.
 3 Q. Did you do any measurements?
 4 A. No.
 5 Q. Did you put your hand under the airstream?
 6 A. Yes.
 7 Q. How long did you run it? Or whoever ran
 8 it? How long did it -- how long was it run?
 9 A. I'd say somewhere in the range of 10 to 15
 10 minutes.
 11 Q. And did that inform your opinions in any
 12 way --
 13 A. No.
 14 Q. -- that experience?
 15 A. No.
 16 Q. If you could turn to page 8 of your
 17 report, Exhibit 1?
 18 A. Page 8?
 19 Q. Yup. In your -- the second full paragraph
 20 on the top of that page you say, "Data from the
 21 CDC's NHSN have demonstrated that surgical
 22 procedure-specific and surgeon-specific SSI rates
 23 are essential." Do you see that?
 24 A. Yes.
 25 Q. And you have no information about the

Page 287

1 surgeon-specific rates in the McGovern study; right?
 2 A. Correct. But I'm specifically there
 3 talking about surveillance data. The NHSN is a CDC
 4 national healthcare safety network that does
 5 nationwide surveillance of healthcare-associated
 6 infections, including surgical site infections and
 7 prosthetic joint infections. So it's talking
 8 specifically about if you're doing surveillance,
 9 those are very important.
 10 Q. How big are the bacteria that cause
 11 peri-prosthetic joint infections?
 12 A. Well, they vary depending upon the
 13 bacteria. But something like Staph aureus is in the
 14 range .4 to .8 microns.
 15 Q. It's your understanding that there are
 16 Staph aureus bacteria that come as small as
 17 .4 microns?
 18 A. Correct.
 19 Q. And where -- do you have any -- anything
 20 you can cite to that would support that?
 21 A. I could get them for you. Probably
 22 microbiology textbooks.
 23 Q. Okay. Have you -- have you looked at a
 24 microbiology textbook any time recently to see if
 25 your recollection of what size a staphylococcus

Page 288

1 bacterium is is correct?
 2 A. I've looked at literature.
 3 Q. Recently?
 4 A. Yeah.
 5 Q. Why?
 6 A. So I'd know the answer to that question.
 7 Q. And based on recent -- this recent
 8 literature review, you found support for the notion
 9 that an individual staphylococcus bacterium can be
 10 as small as .4 microns?
 11 A. .4 to .8 microns.
 12 Q. You've mentioned soot on a number of
 13 occasions; right?
 14 A. Maybe twice.
 15 Q. Okay. And you've mentioned it in your
 16 report; right?
 17 A. Correct.
 18 Q. How big is soot?
 19 A. Probably varies.
 20 Q. What's the range of a soot particle?
 21 A. I'd have to look that up. I'm not sure
 22 offhand.
 23 Q. Is it --
 24 A. It can be -- it can be very similar to
 25 what we're talking about in terms of bugs. In that

Page 289

1 the bacteria like Staphylococcus could be one single
 2 organism. It could be two, it could be 10, it could
 3 be 100, it could be on a skin squame, it could not
 4 be. So it's -- you know, it varies. And the same
 5 thing with soot. It could be one particle or it
 6 could be many particles in aggregate.
 7 Q. Could a soot particle be smaller than an
 8 individual staphylococcus bacterium?
 9 A. I don't know. I'd have to look it up.
 10 Q. You didn't look it up before you concluded
 11 the fact that soot particles escaped the Bair Hugger
 12 blanket means that bacteria can escape a Bair Hugger
 13 blanket?
 14 A. Repeat that question, please?
 15 Q. Well, you didn't -- one of your -- one of
 16 the bases of your opinions is the poster at the MD
 17 Anderson center in Texas where water got into a Bair
 18 Hugger somehow or -- and shorted out the circuitry
 19 and an electrical fire or something ensued and soot
 20 came out of the blanket onto the patient; right?
 21 A. It probably was on the floor, huh?
 22 Q. The soot?
 23 A. No. The Bair Hugger.
 24 Q. No, I'm talking --
 25 A. That's how it got water on it.

Page 290

1 Q. Well, you -- do you know how it got water
2 on it or in it?

3 A. I'm assuming it probably was on the floor.

4 Q. Okay. But it's just an assumption on your
5 part?

6 A. Correct.

7 Q. Okay. But I'm talking about the soot that
8 you -- you referred to in your report. You --

9 A. Okay.

10 Q. -- point to that as evidence that bacteria
11 can get onto the blanket; right?

12 A. Correct.

13 Q. But you -- before you rendered that
14 opinion, you didn't look to see if soot particles
15 could be substantially smaller than bacteria, did
16 you?

17 A. I didn't go look up particulates.
18 Obviously the studies of particulates have looked at
19 a variety of different sizes. So the smallest sizes
20 that they've looked at is I believe about 3 mi- --
21 .3 microns. So it's somewhere in the range of Staph
22 aureus. Plus we know from microbiologic studies
23 that Staph aureus can make it through a .22 or .45
24 micron filter. So I suspect that the holes in the
25 Bair Hugger are bigger than that.

Page 291

1 Q. So your understanding is that a soot
2 particle doesn't get any smaller than .3 microns?
3 Is that what you're saying?

4 A. No. What I'm saying is that when they're
5 doing their particulate studies, they look at a
6 variety of different sizes, which I suspect soot can
7 do as well. And that one of those sizes is about .3
8 microns. And my guess is it's -- some soot
9 particles can be about that size.

10 Q. But it's just a guess on your part; you
11 didn't do anything to look into that, did you?

12 A. I didn't. I mentioned that.

13 Q. So if soot particles could be as small as,
14 say, .1 micron, then the fact that a bunch of
15 .1 micron soot particles got out of a Bair Hugger
16 blanket doesn't tell you anything about whether
17 larger bacteria would or would not get out of that
18 blanket, does it?

19 MR. B. GORDON: Objection to form. Lack
20 of foundation. Calls for facts not in evidence.

21 THE WITNESS: Well, that assumes that they
22 kind of line up individually and run through the
23 blanket, they don't aggregate, and that none of them
24 are larger sizes than that. And I don't know that
25 that's true.

Page 292

1 BY MR. C. GORDON:

2 Q. Fair enough. So I -- I was asking about
3 individual, single -- a single bacterium. You're
4 saying -- you're saying that bacteria actually tend
5 to aggregate; right?

6 A. Well, I didn't say they tend to; I said
7 they could.

8 Q. Well, is it typical for an individual
9 bacterium to float around all by its lonesome?

10 A. Like I said, it depends on the bacterium
11 you're talking about.

12 Q. I'm talking about --

13 A. Certainly Mycobacterium tuberculosis does
14 that.

15 Q. I'm talking about the ones that cause
16 peri-prosthetic joint infections, the prominent
17 ones.

18 (Reporter asks for repetition.)

19 Let's talk about staphylococcus. Does
20 staphylococcus -- do staphylococcus bacteria tend to
21 cluster together, or do they float around as
22 individuals?

23 A. Well, I don't know that anybody really
24 knows the answer to that. But they probably more
25 likely are on skin squames.

Page 293

1 Q. How big is a skin squame?

2 A. Probably in the 5- to 10-micron range.

3 Q. A lot bigger than soot; right?

4 MR. B. GORDON: Objection to form --

5 THE WITNESS: It depends on --

6 MR. B. GORDON: -- assumes facts not in
7 evidence.

8 THE WITNESS: It depends on if the soot is
9 aggregated or not.

10 BY MR. C. GORDON:

11 Q. You have no idea how big the soot was that
12 came out of the blanket at the MD Anderson center in
13 Texas, do you?

14 A. I don't believe they provided any sizing.

15 Q. And they didn't provide any analysis
16 whereby they were -- tried to extrapolate from the
17 finding that soot came out to the question of
18 whether bacteria could come out of the blanket, did
19 they?

20 A. I don't remember if they speculated on
21 that or not. I think it was more just a description
22 of what happened and that it raised their concern
23 that bacteria could come out. And that the
24 allegation or hypothesis that the blanket was a
25 secondary filter was not true.

Page 294

1 Q. And when you talk about -- strike that.
2 When you talk about the soot coming out of
3 the blanket, the MD Anderson situation, you used
4 that as support for your conclusion that the Bair
5 Hugger is capable of emitting bacteria, you're just
6 speculating too; aren't you?

7 MR. B. GORDON: Objection to form.

8 THE WITNESS: I don't know that I'd call
9 it speculation. I put that in the context of all
10 the other materials that I reviewed in terms of
11 bacteria size, in terms of particles being generated
12 by the Bair Hugger machine.

13 You know, so the fact that soot has made
14 it through the blanket, to me adds additional
15 information to that, suggesting that if that
16 contaminated air is blown into the blanket, that why
17 is it going to be filtered any more than the soot
18 would be --

19 BY MR. C. GORDON:

20 Q. Even though you --

21 A. -- and it wasn't.

22 Q. Even though you have no idea how big the
23 soot particles were?

24 A. Well, I know the soot particles aren't
25 giant. You were saying they might be smaller.

Page 295

1 Maybe they are, maybe they're not.

2 Q. And if they're smaller, that could mean
3 that particles that are significantly smaller than
4 bacterium might be able to get through the blanket,
5 but that doesn't necessarily mean that
6 bacteria-sized particles can get through the
7 blanket?

8 MR. B. GORDON: Objection; lack of
9 foundation.

10 THE WITNESS: Well, and, again, that
11 supposes that one little particle of soot is going
12 through. And it seems like from the pictures that
13 they showed there were more than aggregates.
14 Aggregates are more pieces of particles than one.
15 That they basically were the size of the hole.

16 BY MR. C. GORDON:

17 Q. You're talking about a picture that you
18 saw, or did you actually see the soot?

19 A. No. Picture of the patient with the
20 little dots.

21 Q. And you -- and it's your understanding
22 that each dot represented a single soot particle?

23 MR. B. GORDON: He didn't say that.
24 Objection to form.

25 THE WITNESS: No. It's exactly the

Page 296

1 opposite of what I'm saying. That I think it
2 illustrates that there's more than one particle
3 coming through that blanket hole. And that it may
4 well represent aggregated soot, in which case the
5 size may be in fact larger than a bacteria.

6 BY MR. C. GORDON:

7 Q. You say "may be aggregated." So it may
8 not be; right?

9 MR. B. GORDON: Objection to form.

10 THE WITNESS: Well, I think it probably
11 is.

12 BY MR. C. GORDON:

13 Q. Based on what?

14 A. Based on the size of the dot.

15 Q. On page 16 of your report you -- in the
16 third full paragraph down, middle of the paragraph
17 where you talk about, "The previously mentioned
18 studies have shown that" -- et cetera, et cetera,
19 "Bair Hugger FAW exhausts bacterially contaminated
20 air into the OR."

21 Do you see that sentence or that part of
22 the sentence?

23 MR. B. GORDON: Page 13?

24 MR. C. GORDON: Page 16.

25 MR. B. GORDON: Sorry. Thank you.

Page 297

1 BY MR. C. GORDON:

2 Q. It says "exhausts bacterially contaminated
3 air into the OR." That part of the sentence that I
4 want to talk about.

5 A. Correct.

6 Q. What study or studies have demonstrated
7 that Bair Hugger exhausts bacterially contaminated
8 air into the OR?

9 A. Well, I think it's a constellation of
10 studies, number one. So it's studies showing
11 through swabbing air cultures, even rinses of the
12 hoses had bacteria that contaminated air is exiting
13 the hose. Together with the example of the soot
14 making it through the blanket showing it's not a
15 secondary filter. Plus the numerous studies showing
16 that the Bair Hugger increases particulates in the
17 sterile field. So it's really a conglomeration of
18 those.

19 MR. C. GORDON: Let's take a break.
20 Nearing conclusion. I just want to go over my
21 notes.

22 THE VIDEOGRAPHER: The time is 5:03 p.m.
23 We're off the record.

24 (Recess taken from 5:03 p.m. to 5:16 p.m.)

25 THE VIDEOGRAPHER: This marks the

Page 298

1 beginning of Volume I, file 6 in the deposition of
2 Dr. William Jarvis. The time is 5:15 p.m. and we're
3 on the record.

4 (Exhibit 26 marked.)

5 BY MR. C. GORDON:

6 Q. Dr. Jarvis, I'm going to show you what's
7 been marked as Jarvis Exhibit 26. Is that what
8 it --

9 A. Twenty- -- yeah.

10 Q. And it was previously marked as McGovern
11 Exhibit 6.

12 I just want to ask if you've seen this
13 before.

14 A. I don't think so.

15 Q. Do you recall reading Dr. -- strike that.

16 Dr. McGovern's deposition was one of those
17 depositions that was not on your reference list --
18 strike that.

19 Dr. McGovern's deposition was not listed
20 in your December 2016 billing. It hadn't occurred
21 as of then. But it shows up on your "Additional
22 Materials" list now. Do you know if you read
23 McGovern's deposition before or after you rendered
24 your opinion on March 31?

25 MR. B. GORDON: Objection. It was asked

Page 299

1 and answered this morning.

2 MR. C. GORDON: I'm sure it was and I --

3 THE WITNESS: Yeah, I don't remember.

4 BY MR. C. GORDON:

5 Q. Okay. And when you read the McGovern
6 deposition, do you remember reading any discussion
7 of experiments that they attempted to do in
8 Northumbria to simulate a surgical procedure and
9 measure particles in bacteria using the Bair Hugger
10 versus HotDog? Or just -- I think it was just Bair
11 Hugger on or off.

12 A. So you're not talking about the bubble
13 study at all?

14 Q. Not the bubble study. Completely separate
15 study. Simulated surgery where they're measuring
16 particles and bacteria.

17 A. Yeah, I don't remember.

18 Q. So in this particular study, where the
19 results show, "The experiments showed no notable
20 increase in either ambient particle count or
21 bacterial count in the vicinity of an operative
22 field when a forced air warming device was used in a
23 normal intraoperative manner, there was an increase
24 in local particle counts only when the surgeon
25 enters the operative field from outside the laminar

Page 300

1 flow boundary."

2 That's the first you've heard this, I take
3 it?

4 A. Well, I'm thinking now, I'm wondering if
5 this was part of an abstract that was submitted to a
6 meeting that was not accepted and he was talking
7 about negative results.

8 Q. Okay.

9 A. If that's the one, then, yes, I remember
10 him describing it.

11 Q. And this is not -- you're right. There
12 was an abstract. But this is not the abstract.
13 This is the --

14 A. No, no, no. But I mean, I think that's
15 the context that he was discussing it --

16 Q. Okay. So --

17 A. -- was that there was an abstract
18 submitted to a UK orthopedic meeting and it hadn't
19 been accepted.

20 Q. Did you con- -- well, strike that.

21 You didn't mention anything in your report
22 about the attempt on the part of McGovern and Reed
23 to count particles or bacteria in simulated
24 operating room or simulated operation when the Bair
25 Hugger was on; right?

Page 301

1 A. Correct.

2 Q. You didn't think that was relevant or
3 important to your opinions?

4 A. Well, I think the only thing I knew about
5 it was what he said in his depo, which was pretty
6 brief. Didn't go into detail about the methodology
7 or the results.

8 Q. Did you ask to see the exhibits?

9 A. No.

10 (Exhibit 27 marked.)

11 BY MR. C. GORDON:

12 Q. Let me show you what's been marked as
13 Exhibit 27. Previously marked -- collection here --
14 Augustine 60 and Gauthier 26.

15 You did not read the deposition of
16 Dr. Gauthier; right?

17 A. No.

18 Q. Or Dr. Augustine; right?

19 A. Correct.

20 Q. So do you recall if you've seen this
21 document before, couple of e-mails from July of
22 2010?

23 A. I don't think I've seen this, no.

24 MR. C. GORDON: I have nothing further.
25 Thanks.

1 MR. B. GORDON: We've got about an hour.
2 Do you want to take a break?
3 (Laughter.)

4 MR. B. GORDON: Actually, I think I might
5 want to ask one little quick question.

6 MR. C. GORDON: Do you need to switch?

7 MR. B. GORDON: For seats?

8 MR. C. GORDON: Yeah.

9 MR. B. GORDON: No. Unless you want me
10 to.

11 MR. C. GORDON: It's up to you.

12 EXAMINATION

13 BY MR. B. GORDON:

14 Q. Dr. Jarvis, you gave a lot of testimony
15 this morning about the things that you did to frame
16 or render your opinion as set forth in your report
17 today. Do you recall that testimony?

18 A. Vaguely.

19 Q. Okay. I just want to have it clear for
20 the record. Could you just take us through for the
21 members of the court and the jury that may see this
22 or read this, the scientific process that you
23 followed in attempting to answer the question that
24 you were looking at in this case concerning whether
25 the Bair Hugger device was unreasonably dangerous or

1 not? And in that description include everything
2 that you did, and not just the literature that you
3 were questioned about, but everything and every part
4 of the process that you followed in line with your
5 CDC training.

6 MR. C. GORDON: Object to the form of the
7 question.

8 THE WITNESS: Well, given my background
9 and training in infectious disease and epidemiology
10 and my time at CDC, being in charge of outbreak
11 investigations, guideline development, and the
12 surveillance system, using that knowledge and
13 expertise to then try to evaluate all the different
14 possibilities associated with the Bair Hugger.

15 So I did numerous Google and PubMed
16 searches of a variety of different bacterial
17 contamination of Bair Hugger units of was there data
18 to associate Bair Huggers with increased particles
19 in the sterile field. What is the impact of Bair
20 Huggers on laminar airflow. What the Bair Hugger
21 does in terms of airborne contamination and SSI
22 risk. And the correlation between particles and
23 microbes. So as many different combinations and
24 permutations as I could of basically normothermia
25 particles, airborne contamination.

1 I then reviewed the characteristics of the
2 Bair Hugger device in terms of description on the
3 internet, visualization of the product.

4 Then looked at the data on both published
5 data as well as 3M data and data from a variety of
6 depositions and exhibits. On how the Bair Hugger
7 device was submitted for 510(k) with the description
8 of having a high particulate air filter and how that
9 was changed to MERV 14 filter. And then from the
10 500 series to the 700 series, downgraded to even
11 less than that. How 3M had done studies
12 specifically of the filter not in the device but in
13 artificial laboratory setup showing its MERV 14
14 filter. But at least two studies done of the filter
15 efficiency in vivo being closer to -- at least in
16 the 700 series -- being closer to 60, 65 percent.

17 Looking at exhibits from 3M about their
18 own concern about the efficacy of the filter and
19 Project Ducky. And even though a variety of
20 different methods including HEPA filtration were
21 considered, none were implemented.

22 Looking at studies even from Sessler
23 showing increase in in particulates associated with
24 the Bair Hugger device and repeated requests from
25 Dr. Sessler that 3M do a study comparing the Bair

1 Hugger with other warming devices.

2 Looking at the various depositions from
3 Sessler, Kurz, as well as the others that have done
4 these studies, particularly the McGovern study
5 showing that -- neither McGovern nor Reed received
6 any compensation for doing this study -- that they
7 collected all of the data both from the bubble study
8 as well as from the periods where the HotDog and
9 Bair Hugger were used. And working with Albrecht to
10 analyze that data and write the papers.

11 And to critically look at all of these
12 different papers that addressed all of these
13 different issues.

14 And really to me it's the comprehensive
15 nature of all of that that leads me to believe that
16 the Bair Hugger is a dangerous device and can cause
17 surgical site infections, particularly in patients
18 that have prosthetic joint implants.

19 Q. And to be clear on that, when you say
20 surgical site infections in patients with prosthetic
21 joint devices, you mean periprosthetic or deep joint
22 infections?

23 A. Absolutely.

24 MR. C. GORDON: Objection; leading.

25 THE WITNESS: Absolutely.

Page 306

1 BY MR. B. GORDON:

2 Q. And your opinions as you just stated and
3 the documents you referenced, most of those are
4 expressed in your report that you've issued in this
5 case; is that right?

6 MR. C. GORDON: Same objection.

7 THE WITNESS: Right. And I certainly
8 looked at, you know, like Dr. Elghobashi's work and
9 looked at others as well in the literature. And --
10 so I've certainly looked at not only depositions but
11 reports. I looked at and evaluated critically
12 Dr. Samet, Dr. Elghobashi, and other reports.

13 BY MR. B. GORDON:

14 Q. And do you hold all these opinions to a
15 reasonable degree of medical and scientific
16 probability?

17 A. Yes.

18 Q. And have -- have you ever had an
19 opinion -- an expert opinion be limited or excluded
20 from consideration by a jury by any court in this
21 land?

22 A. No.

23 MR. B. GORDON: Thank you, Doctor.

24 FURTHER EXAMINATION

25 BY MR. C. GORDON:

Page 307

1 Q. You made reference to MERV 14.

2 A. Correct.

3 Q. What is that?

4 A. MERV 14 is an ASHRAE category filtration
5 for devices. They have MERV categories ranging from
6 1 to used to be 20, but now it's to 17.

7 Q. You said it's a category for devices. Do
8 you mean medical devices?

9 A. Well, it's -- no, it's specifically been
10 recommended for ventilation systems.

11 Q. For hospital ventilation systems; right?

12 A. Well, that would be one of them, yes.

13 Q. Well, what -- what's a MERV 14 recommended
14 for?

15 A. Recommended for operating rooms or higher.
16 HEPA filtration, too.

17 Q. But as far as ASHRAE is concerned, the
18 MERV 14 is adequate for an operating room?

19 A. For general --

20 Q. Let me finish.

21 -- ventilation system; right?

22 A. Well, they actually have two filters. So
23 there's a pre-filter and then the MERV filter. So
24 two filters are used. But the MERV filter has the
25 highest filtration efficiency.

Page 308

1 Q. And I think --

2 A. And it's for, as you say, general surgical
3 operating room.

4 Q. And I think I heard you say that 3M
5 downgraded the filter from MERV 14?

6 MR. B. GORDON: Objection;
7 mischaracterizes his testimony.

8 BY MR. C. GORDON:

9 Q. And I don't mean to mischaracterize him.
10 I may have misheard you.

11 A. Well, the initial 510(k) of the 500 series
12 was supposed to be initially a HEPA filter, when the
13 510(k) was submitted according to 3M documents. And
14 then it was changed. It looks like never told FDA
15 that it was not a HEPA filter that was placed but,
16 rather, a MERV 14 filter.

17 And that MERV 14 filter when tested
18 outside -- so just taking the filter and putting it
19 in a nice box where it's very tight and then
20 challenging it, which 3M did twice -- basically met
21 the criteria for a MERV 14 filter. But at least two
22 investigators in peer-reviewed journals that did
23 testing specifically of a filter from those devices,
24 both a 500 series and a 700 series in use in a Bair
25 Hugger, found that the filtration was much lower

Page 309

1 than -- than that.

2 And from e-mail discussions with 3M
3 personnel, it sounds like they were well aware that
4 they, number one, didn't put a HEPA filter in and
5 then, number two, that it might not even meet MERV
6 14 criteria.

7 Q. Is it your understanding that the filter
8 in the Bair Hugger today is not MERV 14?

9 A. Well, all I can say is that testing of it
10 in -- of an in-use device, device being used in a
11 hospital, was, I believe, 63 percent or .3-micron
12 challenge.

13 Q. And that was a study financed by Scott
14 Augustine; right?

15 A. Well, I'd have to look back at the study.
16 I don't know that he financed it or not. That
17 doesn't change the result.

18 MR. C. GORDON: Nothing further.

19 MR. B. GORDON: Nothing further 'til
20 trial.

21 THE VIDEOGRAPHER: This marks the end of
22 Volume I, file 6 and concludes the deposition of
23 Dr. William Jarvis. The time is 5:33 p.m. We're
24 off the record.

25 (Discussion held off the record.)

1 MR. B. GORDON: So, Doctor, you have the
2 right to read and sign your deposition. Would you
3 like to exercise that right?

4 THE WITNESS: Yes.

5 (The proceeding adjourned at 5:35 p.m.)

6
7 WILLIAM R. JARVIS, M.D.

8 Subscribed and sworn to before me
9 this day of 2017.

1 CERTIFICATE
2 STATE OF CALIFORNIA)
3 : Ss
4 COUNTY OF CONTRA COSTA)

5 I, Heidi Belton, a Certified Shorthand
6 Reporter, a Registered Professional Reporter, a
7 Certified Realtime Reporter, California Certified
8 Realtime Reporter, and Certified LiveNote Reporter
9 within and for the State of California, do hereby
10 certify:

11 That WILLIAM R. JARVIS, M.D., the witness
12 whose deposition is herein before set forth, was
13 duly sworn by me and that such deposition is a true
14 record of the testimony given by such witness.

15 I further certify that I am not related to
16 any of the parties to this action by blood or
17 marriage and that I am in no way interested in the
18 outcome of this matter.

19 In witness whereof, I have hereunto set my
20 hand this 4th day of August, 2017.

21
22
23 HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR
24 Certified Shorthand Reporter No. 12885
25

1 INDEX
2 WITNESS: WILLIAM R. JARVIS, M.D.

3
4 EXAMINATION PAGE
5 BY MR. C. GORDON 6, 307
6 BY MR. B. GORDON 302

EXHIBITS	PAGE
Exhibit 1 Document titled "Expert Report of Dr. William R. Jarvis"	6
Exhibit 2 Collection of invoices	8
Exhibit 3 Document titled "Jarvis Additional Materials Reviewed"	26
Exhibit 4 Document titled "Can Particulate Air Sampling Predict Microbial Load in Operating Theatres for Arthroplasty," by Cristina, et al.	47
Exhibit 5 Document titled "Guideline for Prevention of Surgical Site Infection, 1999"	51
Exhibit 6 Document titled "Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017"	57
Exhibit 7 Document titled "Supplementary Online Content"	60
Exhibit 8 Document titled "Electronic particle counting for evaluating the quality of air in operating theatres: a potential basis for standards?"	86
Exhibit 9 Document titled "Universal Screening for Methicillin-Resistant Staphylococcus aureus by Hospitals"	118
Exhibit 10 Document titled "Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial," by Oguz, et al., 2017	107

1	INDEX OF EXHIBITS (continued)	
2	PAGE	
3	Exhibit 11 Article titled "Comparison of	123
4	central line-associated	
5	bloodstream infection rates	
6	when changing to a zero fluid	
7	displacement intravenous	
8	needleless connector in acute	
9	care settings"	
10	Exhibit 12 Document titled "Retraction	126
11	notice"	
12	Exhibit 13 Retracted article from	127
13	American Journal of Infection	
14	Control	
15	Exhibit 14 6/29/17 e-mail to Dr.	132
16	Darouiche from Dr. Jarvis	
17	Exhibit 15 Document titled "Forced-air	139
18	warming discontinued:	
19	periprosthetic joint infection	
20	rates drop"	
21	Exhibit 16 Document titled "Prophylactic	169
22	Antibiotics Against Early and	
23	Late Deep Infections After	
24	Total Hip Replacements"	
25	Exhibit 17 Document titled "Seminars in	182
	Infection Control"	
	Exhibit 18 Spreadsheet, five pages	192
	Exhibit 19 Handwritten notes from various	197
	depositions	
	Exhibit 20 Handwritten notes	197
	Exhibit 21 Document titled "Risk Factors	204
	For Wound infections After	
	Total Knee Arthroplasty"	

1	INDEX OF EXHIBITS (continued)	
2	PAGE	
3	Exhibit 22 Document titled "Transmission	244
4	of Mycobacterium chimaera from	
5	Heater-Cooler Units during	
6	Cardiac Surgery despite an	
7	Ultraclean Air Ventilation	
8	System"	
9	Exhibit 23 Augustine research report	258
10	Exhibit 24 Document titled "Healthcare	260
11	Infection Control Practices	
12	Advisory Committee, December	
13	1-2, 2016"	
14	Exhibit 25 Document titled "Draft Device	266
15	Selection Algorithm"	
16	Exhibit 26 Document titled "Do Forced Air	298
17	Warming Devices Increase	
18	Bacterial Contamination of	
19	Operative Field?"	
20	Exhibit 27 E-mail string, latest-in-time	301
21	dated 7/18/10 at 20:11	
22		
23		
24		
25		

1	ERRATA SHEET
2	Case Name:
3	Deposition Date:
4	Deponent:
5	Pg. No. Now Reads Should Read Reason
6	_____
7	_____
8	_____
9	_____
10	_____
11	_____
12	_____
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14	_____
15	_____
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20	
21	Signature of Deponent
22	SUBSCRIBED AND SWORN BEFORE ME
23	THIS ____ DAY OF _____, 2017.
24	_____
25	(Notary Public) MY COMMISSION EXPIRES: _____

A				
A-L-B-I-D-U-S (1) 256:2	203:2	addressed (2) 138:4 305:12	140:6,14 144:5	81:15
A-L-B-R-E-C-H-T ... 96:10	202:21	addresses (1) 72:14	176:4 188:6 270:20	air/water (21) 266:25 267:5,7,8,13
A-V-I-D-A-N (1) 255:8	acknowledged (1) 106:5	Addressing (1) 90:21	agree (23) 23:18 44:4 48:5,15	268:3,6,8,17,23
a.m (7) 2:2 5:3,13 76:24 77:1	acknowledges (2) 197:17 249:11	adds (2) 23:25 294:14	50:21 71:20 72:8	269:8,13,14 270:2
77:1,4	Act (1) 278:4	adequate (2) 183:20 307:18	78:11 82:18 84:22	270:18,24 271:8,12
ability (1) 268:25	action (2) 130:11 311:16	adequately (1) 18:1	89:10,17 100:20	271:21 273:1
able (8) 17:24 32:22 209:20	Actions (1) 1:8	adjoined (1) 310:5	126:4 128:9,13	274:10
217:9 232:17 240:3	active (8) 100:21,24,24 101:2	administration (3) 222:2 232:7 246:19	152:6 165:4 175:19	airborne (18) 46:14,21 50:6 72:3
282:20 295:4	119:2,6,16,16	Administrator (1) 2:12	185:3 189:13	87:12,14,22 88:2
abnormal (1) 210:16	activities (8) 19:25 46:23 72:5	advance (1) 158:20	194:15 264:2	91:7 107:16 183:15
abscess (1) 167:14	135:12 137:17	advantage (1) 83:11	agreed (1) 109:9	184:7,14 255:2,3
absence (2) 82:9 114:8	156:4,12,14	advantages (1) 213:8	agreement (2) 138:16 139:10	303:21,25 313:23
absolutely (13) 12:1 125:14 126:7	activity (8) 86:4 88:10,25 92:6,16	advice (1) 52:6,6,8,16 55:5,17	agreements (1) 10:12	airflow (11) 247:14,16 248:3,8,11
141:1 151:9 152:5	173:18,19 174:13	135:14 137:8,8	agrees (1) 264:21	248:17,24,25
158:17 185:6	actual (8) 108:14 206:12 250:17	315:9	Ah (1) 206:18	249:17,19 303:20
213:15 225:3	251:4,19 278:17	advocate (2) 120:24 196:3	aim (1) 171:23	airstream (4) 255:18 257:8,19
243:22 305:23,25	281:5,16	aerosolized (4) 177:9 185:7 246:12	aimed (2) 156:12 171:11	286:5
abstract (5) 245:14 300:5,12,12	acute (1) 314:5	273:24	air (79) 1:4 5:7 35:19,22 36:1	akin (1) 239:20
300:17	adding (1) 268:10	agor (12) 100:12,21 254:11	69:6 71:1 81:7 82:5	al (5) 73:7 84:9 107:18
abstracted (1) 216:12	addition (6) 7:14 30:24 178:21	255:11,14,15	82:20,21 93:20	313:9,25
abstracts (1) 31:18	215:12 224:23	256:10,17,23,25	94:21,22,24 100:24	Albidus (1) 256:2
accent (2) 84:25 85:4	277:25	257:4,18	101:2 105:10	Albrecht (12) 96:9 142:17 143:19
accept (1) 165:17	additional (35) 25:23 26:9,20,21	age (4) 213:25 239:13,16,18	146:24 167:3 183:2	144:2 145:18,19
acceptance (1) 147:22	32:13 40:11,13 41:9	agency (3) 139:5 201:15 277:11	198:4 245:25	190:8,11 200:7
accepted (4) 148:13 188:12 300:6	47:3,12 60:25 68:21	agent (2) 137:16 183:6	246:13,13 249:11	258:17 260:2 305:9
300:19	108:1 117:14	agents (1) 175:5	249:14,15 251:8,25	Albrecht's (1) 259:24
account (6) 152:17 154:5 163:18	139:12,20 141:13	aggregate (3) 289:6 291:23 292:5	252:1,16 253:15	alcohol (19) 156:8,10 171:6 173:1
181:23 231:3 270:6	142:3 143:21,22	aggregated (3) 293:9 296:4,7	254:3,20 256:5,16	173:3,4,7,8 174:25
accounted (2) 217:11 228:24	146:2,21 193:15	aggregates (2) 295:13,14	256:18,18 257:1,22	174:25 175:4,5,10
accounting (1) 235:21	196:12 198:13	ago (14) 53:23 58:2 61:19	259:5,5 262:15,19	175:10,12,16,17,18
accurate (3) 39:11,20 92:19	216:11 231:25	113:5 117:25	264:17 265:21	177:13
achieve (1) 45:7	237:2 246:4 258:12	132:21,21 138:1	266:3 268:7,17	algorithm (10) 56:23 265:3,8 266:12
Acinetobacter (1)	294:14 298:21		269:8 270:3,21	266:13,13 267:11
	313:5		271:9,11,21,23,25	268:1 271:2 315:11
	additions (2) 7:21 55:7		272:4,20 273:2,3,11	allegation (1) 293:24
	address (10) 36:24 44:9 65:11		273:23,25 274:8	allegations (2) 66:15 67:13
	73:15 86:6 137:10		285:21 294:16	alleging (1) 66:17
	153:19 163:6 188:3		296:20 297:3,8,11	allowed (2) 138:21 277:24
	274:20		297:12 299:22	Altameier (1) 154:24
			304:8 313:7,17	alternative (6)
			315:5,12	
			air-conditioning (1) 219:5	
			air-sucking (1)	

87:6 88:1 89:4 93:2 93:5,5 ambient (1) 299:20 amendment (1) 165:18 America (2) 18:14 60:15 American (3) 148:22 214:9 314:9 amount (6) 39:2 40:2 49:22 73:25 180:7 268:9 analyses (5) 227:16,22 229:19,24 231:12 analysis (21) 86:18 114:4 130:19 131:7,12 134:9 163:19,21 189:4 211:12 213:18 228:6 230:14 232:16,16 233:4,6 236:4 237:8 283:10 293:15 analyze (1) 305:10 analyzed (2) 216:13 241:17 and/or (4) 27:4 204:3 257:25 272:4 Anderson (3) 289:17 293:12 294:3 Anderssen (3) 73:17 74:1 101:3 Andersson (1) 73:22 anecdotal (1) 219:24 anesthesiologist (4) 215:1 226:2,19 249:9 anesthesiologists (3) 214:9,14 215:6 anesthesiology (2) 34:5 219:9 Angeles (1) 14:21 anomaly (1) 208:21 answer (40) 17:24 20:24 21:21,25 22:2 44:10 65:20,21 66:1 68:6 83:9 96:16 98:15 110:25 113:24 115:18	116:7 133:19 134:2 134:11,19 135:7 136:11 150:1 153:13 178:25 206:14 210:10 240:9,13 241:16 243:21 252:10,13 253:9 269:10 271:18 288:6 292:24 302:23 answered (27) 18:1 30:17 37:5 68:11 91:24 94:3 98:11 99:1 113:24 129:11 129:16 130:23 138:25 149:25 157:20 163:3 178:12 184:9 238:24 242:22 251:23 252:8 253:23 271:15 273:5 283:1 299:1 answering (1) 268:24 answers (1) 254:18 antibiogram (3) 161:2,4,25 antibiotic (4) 58:18,22 161:12 170:15 antibiotics (7) 156:6 169:1,9 170:8 171:8 186:25 314:15 antibody (1) 58:22 antimicrobial (3) 220:21,25 222:1 antisepsis (1) 156:7 anybody (6) 15:14,19 138:11,23 139:6 292:23 anyway (2) 140:19 157:23 apart (3) 234:17 245:11 284:4 apparently (3) 24:17 75:20 128:22 appear (3) 7:1 26:16 32:17 appearance (1) 14:7 APPEARANCES (1) 4:1	appears (5) 19:14 36:22 47:10 118:11 266:12 appendices (1) 56:22 applications (4) 137:4,13 176:5,7 applied (7) 28:3,11 44:23 51:23 64:22 65:2 155:23 applying (1) 164:10 apprised (2) 21:20 25:8 approach (14) 28:4,10 54:25 57:17 59:3 60:13,18 62:10 68:13 119:19 120:22 121:9,19 185:15 approaches (3) 60:19 121:24 122:12 approvals (1) 277:13 approve (1) 277:17 approved (2) 277:13,17 approximately (1) 5:13 April (5) 8:17,22 9:2,14 37:7 area (6) 53:12 149:17 179:11 266:19,22 283:9 areas (1) 172:5 argue (1) 195:11 arguing (1) 117:8 argumentative (21) 39:19 83:24 84:15 98:25 100:5 113:23 118:2 123:12 128:7 142:22 150:14 155:12 232:22 243:20 263:16 270:24 271:11 272:2 273:5,14 282:2 arguments (1) 225:12 arm (1) 193:18 arms (1)	191:12 arrange (1) 137:10 arrangement (1) 125:1 arrival (1) 91:8 arriving (1) 32:4 arthroplasty (8) 69:23 71:4 196:4 205:5,23 222:12 313:8 314:23 arthroplasty-associ... 231:17 arthroscopy (1) 108:20 article (18) 42:11 44:7 47:11,24 56:24 70:2 74:13 86:13 123:16 126:24 127:12,22 180:14,17 199:21 213:16 314:3,8 articles (19) 27:3,20 33:4,6 35:6 41:23,25 46:1,4 56:25 58:4 70:11 71:6,8,12,13 75:24 128:1 149:6 artificial (1) 304:13 ASA (14) 214:10,13 215:9,14 215:18,21 216:10 225:9,18,23 226:20 228:14 230:11 239:21 aseptic (1) 187:1 ASHRAE (2) 307:4,17 aside (1) 96:12 asked (36) 12:2 30:17 37:5 68:10 70:18,19 91:23 94:2 94:7 96:25 97:4,5,6 98:10 99:1,13 113:23 129:10,16 130:22 138:24 149:24 157:19 163:2 178:11 212:5 238:23 242:21 252:7 253:22 271:14 273:5	276:24 280:19 282:25 298:25 asking (19) 11:6 24:12 25:6 114:22,23 165:15 178:2 240:12 251:1 251:2 252:19,24,25 255:1 259:15 271:19 272:17 273:3 292:2 asks (39) 33:20 34:13 35:21 58:14 78:18 80:19 90:14 96:1 97:2 98:2 109:6 113:13 119:5 120:5 122:3 131:9 132:3 136:17 144:16,20 156:9 161:3,7 171:17 173:2,6,16 179:12 194:20 195:22 197:23 200:24 211:14 216:15 252:12 255:7,20 277:3 292:18 aspect (2) 53:17 55:23 aspergillus (4) 203:1 255:23 256:3 256:20 Assaad (22) 3:19 5:25,25 10:2,8 18:11 85:10,16,18 85:21 91:25 131:23 134:19 135:4 144:22 160:7,8,12 180:21 181:2 261:19,22 assess (2) 70:9 191:19 assessing (5) 20:5 82:8 136:7 185:11 214:21 assessment (5) 57:16,23 121:4 214:16 266:2 assist (1) 186:14 assistant (2) 15:25 16:7 assisting (2) 190:4 220:12 associate (1) 303:18 associated (21) 68:2 105:6,20,22
--	---	--	--	--

110:14 124:6 159:18 173:10 182:17,18,22 183:10 208:9 210:15 215:13 216:19 232:11 233:12,24 303:14 304:23 Associates (2) 13:8,11 association (3) 5:16 60:16 161:25 assume (9) 19:1,17 93:12 135:10 164:11 190:20 195:14 211:10,18 assumed (1) 245:7 assumes (8) 23:23 126:13 179:7 180:2 188:25 202:14 291:21 293:6 assuming (2) 265:13 290:3 assumption (1) 290:4 assurance (1) 125:18 Atlanta (3) 9:2 12:18 16:20 attached (2) 285:11,12 Attachment (2) 7:7,15 attacked (1) 133:5 attacking (5) 133:1,14,23 134:7,25 attempt (2) 74:2 300:22 attempted (5) 23:14 104:15 254:11 254:17 299:7 attempting (1) 302:23 attendees (2) 14:17 15:16 attention (6) 61:23 108:8 154:15 224:20 270:3 271:24 attorney (6) 3:5,12,19 4:5 5:18 135:6 attributable (1)	95:9 attributed (1) 194:14 August (7) 8:18 14:9,9,25 36:17 37:17 311:20 Augustine (17) 34:15,19 139:14,19 142:25 146:1 150:6 258:5,17,21 259:2 259:17,23 301:14 301:18 309:14 315:7 Augustine's (2) 142:14 143:6 aureus (31) 8:1 159:19 161:5,12 162:18 168:18,19 174:11,16 185:5 192:12,15,18 193:8 193:11,13,20,23 194:16 195:3,8 196:13 202:9,12,22 251:14 287:13,16 290:22,23 313:21 authenticated (2) 194:2,5 author (2) 126:8 190:12 authority (3) 236:7,23 263:24 authors (9) 48:7,17 93:15 112:23 126:8 149:4,15,22 182:24 availability (1) 148:25 available (7) 61:21 69:4 188:9 239:4,23 240:3 278:4 Avidan (4) 43:5,6 255:6,8 aware (30) 20:18 21:16 22:9,10 22:16,20,22 46:6 66:3,10 67:17 95:7 128:5 139:23 150:2 150:12 156:25 178:14 195:5,9 210:7 212:3 232:23 237:7 253:4 254:16 255:2 257:21 259:1 309:3 awhile (1) 69:9	B B (265) 5:21 7:15 9:20 10:5 11:1 13:22 16:22 18:10,12 20:6,22 21:10,21 23:22 24:23 27:12 29:8,11 30:14,17 37:5 39:18 40:5,20 41:18,21 42:9 44:17 47:13,17 48:9,20 49:14 50:16 54:24 59:24 60:2 64:12 66:12 67:2 68:10 69:10 71:23 72:12,24 75:8,10,15 76:4 78:15 81:22,25 82:14 83:23 84:12 84:15,24 85:3,6,13 86:23 87:11,15,18 87:21 88:13 89:22 90:12,19 91:23 92:1 92:11 93:13 94:1,16 95:22 96:7,10,24 97:3 98:10,25 99:19 99:22 100:4,22 103:12,25 104:18 106:24 109:3,5,7 110:24 111:6,18,21 111:24 112:6,20 113:10,14,22 114:25 115:7,9,15 115:18,22 116:2,13 116:18,23 117:3,6 118:2,7,14 119:22 120:9 122:4 123:11 125:19 126:12 128:7 129:10,16 130:22 133:16,24 134:8 138:24 141:19 142:7,21 145:1 146:8,16 147:17 149:24 150:14 151:4,7 152:10 155:11 157:19 159:3,6 160:21 161:19,22 162:13 163:2 165:10 168:9 169:17 172:16 174:19,22 175:24 176:18,21 178:8,11 179:6 180:1,18 181:5 184:9 186:1 186:10 187:5 189:11,14,23 193:25 194:8,22	202:13 203:12 204:8 207:25 208:24 212:9,22 213:6 215:23 218:18 223:8 224:18 225:16 226:7 228:11 229:21 230:15,17 232:21 235:22 237:19 238:2,23 240:23 241:13 242:21 243:15,20 249:21 251:21 252:7,10,13,21 253:2,7,12,22 254:8 259:6,9,20 260:9 261:21,24 262:2 263:15 267:14,20 268:18,24 269:4,9 270:22 271:10,14 272:1,14 273:4,13 274:1 279:22 280:16 282:1,25 291:19 293:4,6 294:7 295:8,23 296:9,23,25 298:25 302:1,4,7,9,13 306:1,13,23 308:6 309:19 310:1 312:6 B-I-R-G-A-N-D (1) 76:10 B-O-O-N-E (1) 132:5 back (58) 6:24 8:8 17:25 19:13 23:16 32:13 36:8 45:4,21,22 48:13 55:16 63:10 65:1 72:2 77:14 79:22 94:8 95:16 96:15 98:24 112:5,7 117:21 118:10,23 152:15 154:3 162:23 169:7 170:18,19 172:6 180:13,17 187:15 187:15 196:15 198:17 199:18 201:7 211:1 217:17 217:19 224:20 226:17,22 233:3,17 234:5 241:1 245:17 260:17 267:24 268:22 270:15 281:17 309:15 background (10)	16:11 49:21 89:3 91:18 92:25 188:24 189:1,1 242:19 303:8 backup (1) 61:2 bacteremia (4) 168:13,16,20 169:12 bacteria (78) 23:15,19 74:7 79:14 79:18 80:1 82:13,21 82:22 83:7,22 88:11 89:5 91:7,14,22 92:10 93:12 99:15 103:11,19,20,23 105:13 108:12,22 111:4,16 112:18 113:20 114:23,24 144:22 152:8 153:11 160:3 168:15 175:19,21 176:12,15,20 178:4 178:10 179:3,23 251:2,4,13,19 252:5 253:5,20 254:17 255:3 257:18 259:3 259:18 273:23 287:10,13,16 289:1 289:12 290:10,15 291:17 292:4,20 293:18,23 294:5,11 296:5 297:12 299:9 299:16 300:23 bacteria-containing... 86:22 bacteria-sized (1) 295:6 bacterial (30) 48:8,19 50:5 73:16,23 74:20 76:2 83:2,17 86:21 87:7 88:2 89:20 93:2,6,24 94:14 105:8,22,25 107:7,16 111:11 114:7,9,11 299:21 303:16 313:23 315:13 bacterial-containin... 86:21 bacterially (3) 296:19 297:2,7 bacterias (1) 79:18 bacterium (8) 244:20 288:1,9 289:8 292:3,9,10 295:4
---	---	--	---	--

Bair (157) 1:4 5:7 6:14 8:24 11:7 11:21 12:3 14:21 15:10,13,14 18:19 18:22 19:25 20:5,16 20:20 21:19 24:6,16 24:21 25:4 28:24 29:16 30:6 35:23 36:1 65:12 66:4,7 66:17 67:7,12,19,23 68:3,5,18 70:25 93:23 94:4,13 95:9 96:3,22 97:7,24 99:7,8,14,16 101:14 102:13 104:4 105:7 105:8,9,10 106:4 108:13,21 109:25 111:3,15 112:17 113:17,21 138:5,9 138:14,20 139:8 141:14 146:23 147:10 151:1,2,14 159:12 167:2 177:18 190:17 192:16 193:22 194:14,17 195:3,6 197:8,10,12,16 198:8 200:4 202:10 233:6 236:15,16,20 244:25 246:11,14 247:1 248:11,18 249:1,5,8,11 250:2 250:9,11,18,22 251:5,10,15,20 253:5 255:9,18 257:7 259:19 266:16,21 270:10 272:21 283:14,24 289:11,12,17,23 290:25 291:15 294:4,12 296:19 297:7,16 299:9,10 300:24 302:25 303:14,17,18,19,20 304:2,6,24,25 305:9 305:16 308:24 309:8 Baker (1) 250:22 balancing (1) 122:10 ballpark (1) 25:21 base (1) 146:6 based (17)	30:9,12 44:25 54:16 55:20 126:10 134:16 152:23 154:9,11 163:19 185:18 212:6 230:13 288:7 296:13,14 baseline (1) 188:14 bases (1) 289:16 basically (36) 48:2,5,15 53:14 55:9 55:15 61:3 62:20 66:20 69:19 81:15 102:3 120:1 137:8 143:3 164:24 165:21 166:22 167:6 174:7 179:10 179:14 180:7,14 214:15 219:15 226:14 237:1 245:14 260:5,6 261:7 279:7 295:15 303:24 308:20 basis (9) 50:11 134:5,8 211:19 223:6,18 224:2 237:1 313:18 bathing (1) 171:4 baths (1) 177:12 Baudin (2) 3:11 5:23 Baylen (1) 3:6 BCP (3) 86:20 87:6 88:1 BD (3) 123:4,6,10 Becton (1) 123:3 before/after (2) 58:12 175:14 began (1) 195:9 beginning (16) 8:21 46:13 77:3 132:10 154:18 170:20 181:15 202:18 233:11,14 233:22,25 236:19 242:13 244:3 298:1 behalf (5) 5:20,21,24,25 8:3	belief (4) 146:23 147:7 176:2,5 believe (48) 7:5,22 8:25 11:5,17 11:19 12:1,9 16:20 17:1,7,16 18:4 20:8 23:17 33:17,24 34:15 57:7 58:18 61:20 69:2 76:19 87:2 88:6,19 97:25 109:15 112:11 143:8 145:17,21 147:12 191:24 193:4 194:10 197:20 198:18 199:1 252:9 254:9 255:5 260:24 271:23 290:20 293:14 305:15 309:11 Bell (13) 262:7,11,13,18 263:5 264:19,24 265:1,2 271:2 273:9 274:6 279:25 Bell's (1) 266:2 Belton (5) 1:23 2:7 5:16 311:5 311:23 Ben (16) 3:5 5:21 8:16 9:18,23 10:9,16,20 11:9 12:14 26:8 76:22 115:6,8 134:17,24 beneath (1) 247:15 beneficial (1) 171:20 benefit (1) 173:15 Bergstrom (2) 143:19 144:3 Bernardo (1) 250:22 best (4) 176:10 251:23 260:16 268:25 better (11) 92:21 124:16 173:18 173:20 174:13 176:7,10 219:22 222:25 269:23 283:8 beyond (3) 54:9 176:9 203:13	biases (3) 58:8 59:14,14 big (8) 85:21 207:24 270:17 287:10 288:18 293:1,11 294:22 bigger (3) 196:17 290:25 293:3 bill (1) 14:6 billed (6) 25:24 37:8,11,21 38:3 39:16 billing (3) 143:16 276:14 298:20 binding (1) 174:5 binds (1) 173:23 bio-aerosols (4) 102:18,24 103:2,4 bio-burden (1) 152:8 biofilm (1) 269:16 Biomedical (3) 258:18 259:2,17 bioterrorism (1) 183:6 Birgand (3) 76:8,10,20 bit (12) 34:24 52:19 69:12 152:13 155:22 160:12 175:6 186:20 189:8 201:17 207:23 230:7 Blackwell (2) 4:4 5:19 bladder (1) 69:12 blah (7) 269:20,20,21,21,21 269:21,21 blanket (34) 249:12 250:11,18 251:5,12,15,20 252:5 253:6,17,21 254:7 257:4 272:22 285:11,12,13 289:12,13,20 290:11 291:16,18 291:23 293:12,18 293:24 294:3,14,16 295:4,7 296:3	297:14 blood (4) 102:4 173:24 216:20 311:16 bloodstream (4) 120:14 124:1,5 314:4 blowing (3) 167:3 266:3 274:8 blown (2) 256:25 294:16 blows (4) 262:15,19 264:17 265:21 blue (2) 12:7 241:3 board (2) 278:5,12 board-certified (1) 278:8 Board-eligible (1) 278:10 boards (1) 278:11 body (7) 44:3 121:23 139:7 152:12 285:15,15 285:16 books (1) 157:23 Boone (5) 4:11 97:20 132:1,2,4 borrow (1) 79:20 boss (1) 264:21 bothered (1) 131:13 bottom (12) 46:13 88:7,22 199:13 199:17 208:7 247:12 264:11 265:2 267:21 269:11 270:6 bottom-line (1) 85:24 Boulevard (1) 3:20 boundary (1) 300:1 Bovie (9) 101:25 102:2,9,17,20 103:22 104:16,21 105:6 Bovies (2) 102:10 105:18 box (5)
---	---	---	---	--

266:25 267:4,8 269:12 308:19 boxes (1) 59:18 boy (1) 213:2 branch (1) 277:13 break (15) 12:21 69:11 76:23 131:22,23 180:22 180:24 181:1,2,4,9 243:16,23 297:19 302:2 breaks (1) 187:1 Brian (2) 209:16 237:13 brief (1) 301:6 briefly (1) 6:10 bring (1) 177:21 bringing (1) 167:5 brings (2) 152:8 167:19 British (1) 145:1 broad (8) 36:6 53:3,5,7,9,19,21 70:23 broad (2) 50:3 245:3 broadly (1) 71:5 brought (4) 55:16 128:10 155:18 225:6 Brown (2) 34:5,6 bubble (8) 97:25 98:3,4,5 189:8 299:12,14 305:7 bubbles (1) 108:25 Buck (6) 18:3 20:19 22:11,16 23:5 24:13 Buck's (4) 23:2 24:17 31:16,22 bug (2) 151:23,25 bugs (10) 151:24 177:3,14	179:19,19 180:4,6 191:16 260:7 288:25 bunch (1) 291:14 bundles (2) 171:11 172:3 burden (1) 203:24 bureaucracy (1) 277:25 Buren (2) 197:15 199:4 Burke (2) 4:4 5:20 Burkholderia (1) 203:2 busy (1) 158:11 <hr/> C <hr/> C (325) 3:1 5:19 6:7,18 8:8,12 9:21,24 10:4,7 11:10 14:2 16:24 18:13 20:14 21:5,13 22:6 24:2 25:5 26:6 27:13 29:9,18 30:15 30:20 37:6 39:21 40:7,24 41:20,22 42:2,22 44:21 47:8 47:15,21 48:13 49:9 50:10 51:4,8 55:22 57:2,5 59:25 60:6 60:21,23 63:23 64:1 64:7,10,13 66:13 67:3 68:20 69:13,16 71:11,24 72:15,18 73:4 74:15,17 75:18 76:6,22 77:6 78:3 78:21 79:9 80:9 81:23 82:3,16 84:8 84:13 85:2,5,9,12 85:14,17,20 86:11 86:24 87:13,17,19 87:23 88:17 90:4,13 90:15,20 92:7,23 93:21 94:6 95:6,24 96:8,11 97:5,9 98:12 99:12,20,25 100:19 101:1 103:16 104:5 105:1 107:5,12,15 109:22 111:1,12,19 112:4 112:10 113:7,11,16 114:12 115:3,8,12	115:17,20,23 116:11,15,21 117:1 117:5,8 118:5,8,20 120:4,6,9,10,23 122:13 123:20 126:3,17,20 127:20 128:19 129:14 130:2 131:2,21 132:14 133:20 134:4,13,23 135:8 139:2,17 141:24 142:12 143:5 144:21,24 145:2 146:11 147:11 148:1 149:3 150:5 150:17 151:5,16 152:14 156:16 158:8 159:4,22 160:10,15 161:14 161:20 162:6,22 163:10 165:16 168:21 169:15,18 169:22 170:17 172:19 174:20 176:8,19 177:25 178:9 179:1,22 180:3,19,25 181:8 181:18 182:6 184:11 186:7,17 187:14 189:12,18 190:10 192:1,3 194:6,12 195:1 197:1 203:5 204:4 204:21,24 208:2,6 209:6 212:17,23 213:12 216:7 223:15 224:24 225:19 226:11 227:3 228:13 229:25 230:23 233:2,16 234:3 236:13 237:24 238:11,25 241:7,20 243:4,17,23 244:6 244:11,13 250:7 252:3,18,23 253:3 253:10,19,24 254:4 254:12 258:3 259:7 259:13 260:1,17,19 261:20,23 262:1,3 263:21 266:8 267:23 268:14,21 269:2,6,25 271:6,22 272:7,19 273:8,20 274:3 280:3,23 282:14 283:13	292:1 293:10 294:19 295:16 296:6,12,24 297:1 297:19 298:5 299:2 299:4 301:11,24 302:6,8,11 303:6 305:24 306:6,25 308:8 309:18 312:5 C-L-O-S-T-R-I-D-I... 120:7 C-O-R-Y-N-E-B-A... 255:21 C-R-Y-P-T-O-C-O... 256:1 calculate (4) 189:1 205:21 206:10 206:13 calculated (4) 247:16,19 248:8,24 calculator (1) 206:17 California (9) 1:17 2:6,10 5:1,12 277:23 311:2,7,9 call (14) 12:2 13:1 67:16 116:13,14 130:12 131:16,17 137:10 160:19 195:10 237:2,3 294:8 called (17) 19:20 45:18 52:5 81:13 101:24 107:16 137:21,21 156:1 158:9,13 164:15 171:10 213:2 228:4 242:2 277:20 calls (10) 11:2 17:11,13 20:7 118:3 133:18 151:7 159:6 160:21 291:20 campylobacter (2) 144:19,21 capable (1) 294:5 Capital (1) 120:10 capture (3) 259:3,18 260:7 capturing (1) 256:22 cardiac (6) 159:16 214:24 245:6 245:10,19 315:5	Cardo (1) 264:20 care (4) 156:2 249:15 266:19 314:6 career (1) 232:3 careful (1) 138:19 carefully (1) 70:9 carriage (2) 184:25 187:18 carrying (4) 82:22 103:19,20 105:13 case (32) 16:15 18:19 31:6 51:24 52:13 58:13 58:15 59:10 60:11 108:6 123:24 151:14 163:12 168:7 169:1 172:22 186:12,19,21 205:2 218:25 219:1,11 225:14 232:1,13 245:12 257:6 296:4 302:24 306:5 316:2 case-specific (5) 187:10 216:1,6 218:19,20 cases (13) 7:23 8:3,5,6 42:25 106:22,23 168:7 185:16 192:16,18 219:6 246:4 categories (2) 40:1 307:5 categorize (1) 215:2 category (2) 307:4,7 catheter (2) 175:11,11 catheter-related (1) 120:14 causation (5) 187:8,10 216:3,6 218:21 causative (1) 147:2 cause (18) 103:5 109:11 110:8 110:11 151:3 159:15 168:6,7,10 202:24 204:15
---	--	--	---	--

213:10 237:23 242:14 243:5 287:10 292:15 305:16 caused (10) 11:21 66:17 156:20 157:3,11 163:1 165:6,8 193:7 209:8 causes (7) 66:7 67:7,19 150:22 150:23 165:12,19 causing (3) 171:24 240:16,16 cauterize (1) 102:3 cauterizing (1) 102:5 caution (1) 133:19 CCRR (2) 1:23 311:23 CDC (94) 28:5,10,18,22,23 29:20,25 31:3 34:10 43:18 45:6,6 49:22 50:12,15,18,19,22 51:13,22 52:7,8 53:6,25 54:23,25 55:4,9 56:1,21 61:1 62:11,18 63:5,16 64:2,22 65:3,14 66:24 68:9 105:4 135:13 137:7 139:3 152:24 153:20,24 154:10,12 155:4,9 157:6 158:2,9,13 159:2 160:19,25 161:15 162:8 163:22 164:11 181:21 185:10 190:2 209:21 213:2 242:16 245:22 261:4,7 262:9 263:5 263:10,18,24 264:4 264:5,8,10,13,18 277:7,9,10,12,20 278:3,22 279:25 287:3 303:5,10 CDC's (3) 50:24 56:17 286:21 ceiling (2) 247:15 249:20 cement (1) 220:6 cementless (1) 220:7	center (4) 155:25 277:14 289:17 293:12 Centers (4) 51:10 263:13 264:16 313:12 centimeters (2) 255:11 256:9 central (3) 123:25 124:5 314:3 certain (7) 89:25 90:5 126:9 152:12 236:8 241:12 242:12 certainly (47) 9:17 14:18 16:15 17:13 47:22 54:4,6 54:15 72:10 79:10 94:20 110:11 145:5 153:14 157:4 159:18 162:4 174:5 181:24 182:2 186:3 188:3 190:7 191:17 196:5 202:17,20 204:10 211:5,10 212:1 215:21 225:8 229:22 231:20 236:2 240:24 261:17 263:9 264:19 279:8,12 280:2 284:5 292:13 306:7,10 CERTIFICATE (1) 311:1 certification (1) 278:12 certified (10) 2:7,9,10,11 278:5 311:5,7,7,8,24 certify (2) 311:10,15 cetera (10) 42:20,20 55:7 71:4,4 104:23 267:6,6 296:18,18 CFD (12) 23:3 24:14 30:11 31:22 280:7,11 281:2,12,16,20,23 282:23 CFU (6) 73:16,24 80:8 84:6 86:2 95:2 CFUs (38) 46:15,22,24 72:4,6 73:18,18,23 74:4,20	76:2 77:9,12,18 80:12,16,23 81:2,7 81:10,17 82:6,10,13 84:10 86:7 93:17,24 94:14 95:5,8 100:11 100:16 105:12 110:1,5 255:13 256:7 chain (6) 83:5 122:1,4,8,24 264:22 chair (2) 136:16,18 chairman (1) 135:25 challenge (1) 309:12 challenged (1) 164:20 challenging (2) 271:5 308:20 chance (1) 175:20 change (6) 130:11 155:9 194:24 224:13 236:5 309:17 changed (13) 7:11 46:8 55:1,8,21 56:1 119:11 120:20 156:22 196:16 201:15 304:9 308:14 changes (3) 56:14 62:20 196:18 changing (6) 34:9 158:7 164:7 167:4 224:3 314:4 chapter (3) 182:15,25 183:14 characteristics (4) 150:22 151:11,12 304:1 characterization (16) 29:12 44:18 48:10 75:11 89:23 112:21 113:23 141:20 146:17 168:10 189:24 208:25 241:14 260:10 267:15 273:14 characterize (5) 32:16 75:16 117:1 151:18 152:3 characterized (1) 117:3	characterizing (1) 116:8 charge (6) 148:7 149:1 152:25 274:23 276:1 303:10 charged (1) 276:7 charges (12) 13:19 148:16,16,16 148:17,21,21,21,22 148:23,23 149:1 chart (1) 200:19 charts (1) 242:3 chase (1) 210:13 check (1) 98:24 Chernecky (6) 127:6 128:16 129:24 130:13,16 131:18 Chernecky's (1) 128:4 cherry-pick (2) 115:15 116:20 cherry-picking (2) 44:14 88:15 chi-squared (1) 131:8 chimaera (9) 159:16 244:20,21,21 245:9,19 246:1,20 315:4 chlohexadine (1) 177:12 chlorhexidine (31) 156:8,10 171:4,5,16 171:19 172:8,22,25 173:3,4,7,8,11,14 173:22,23,25 174:12,18 175:3,4,9 175:12,17,18 176:3 177:12 195:24 196:9,14 chlorhexidine's (1) 173:17 choosing (1) 44:25 chosen (1) 127:14 Chris (1) 5:23 Christopher (1) 3:12	chronic (2) 214:16,16 Chuck (1) 176:2 circuitry (1) 289:18 circulating (1) 231:22 circulation (1) 285:21 circumstances (2) 90:2 161:16 citation (2) 154:22 165:11 cite (11) 46:17 67:17 72:11,22 74:18 77:7 79:13 95:13 154:6 169:16 287:20 cited (5) 33:14 40:16 73:9 157:12 281:10 citing (1) 164:12 claiming (1) 133:20 clarify (1) 53:22 Clark (10) 76:3,4,14 86:13 89:10 89:15,18 91:1,18 93:9 classification (3) 214:10,13 216:9 cleaned (3) 268:11 270:11 272:5 cleaning (6) 219:8 268:12,23 269:22,24 270:16 clear (13) 32:1,2 67:9,15 83:18 116:17 117:11 165:14 181:19 182:8 216:4 302:19 305:19 clearance (1) 264:10 clearly (1) 88:10 click (1) 71:8 clinical (3) 30:8,24 197:14 clinicians (1) 275:25 close (5)
---	--	--	--	--

78:17 79:3,7 243:15 249:2 closed (1) 219:3 closely (1) 212:14 closer (3) 256:13 304:15,16 Clostridium (1) 120:6 CLR (2) 1:23 311:23 cluster (10) 161:16 186:12,13 203:19 204:13 232:24 234:10,15 235:5 292:21 clustered (2) 209:13 212:13 CMS (1) 156:1 co-authored (5) 123:22 126:25 127:22 128:2 204:25 co-morbid (1) 230:8 coagulase (3) 194:19,21 202:23 Coffin (5) 3:11,12 5:23,23,24 cohort (4) 58:13,15 59:10 60:8 colleagues (5) 54:8,20 196:8 205:3 245:16 collected (8) 142:25 216:12 229:22 241:17,21,23,25 305:7 collecting (2) 229:9 240:13 collectings (1) 236:22 collection (3) 271:2 301:13 313:4 colonization (2) 153:17 167:16 colonized (6) 120:15,16 121:7 153:16,16 168:18 colony-forming (4) 48:8,19 50:4 83:17 color (6) 223:22 224:3,13 225:6 241:2,2 column (2)	166:11 248:2 combination (9) 30:25 35:13,18 161:23 227:17 228:23 231:1 236:5 236:9 combinations (2) 70:25 303:23 come (24) 8:8 24:6 28:5 41:4 59:15 106:3,8 108:8 119:23 217:17 224:9 232:4 242:20 268:21 270:15 274:19 275:12,15 277:12,21 279:4 287:16 293:18,23 comes (6) 94:25 104:24 249:1 250:10 272:22 278:3 coming (30) 24:4 28:11 44:23 50:14 51:24 52:1 64:19 94:22 146:25 185:12 229:11 251:9,20 252:1,2,5 252:16 253:5,15,21 254:3,6,21 255:3 256:24 257:22 259:4,18 294:2 296:3 command (1) 264:23 comment (3) 61:17 129:25 197:19 commenting (1) 201:16 comments (6) 52:17 55:6 61:18 265:15 271:19 272:17 COMMISSION (1) 316:25 commissioned (2) 22:21 282:22 committee (22) 52:6,7,16 55:5,17 127:7 129:2,8,24 130:5 136:1,5,16 137:3,5,8,9,11,21 138:6,9 315:9 committees (4) 52:8 135:14,17,25 common (5) 148:24 158:24 159:25	161:12 202:24 commonly (1) 207:21 commonsense (1) 176:2 communicated (5) 138:11,19,20,23 139:6 communication (6) 11:25 12:13 18:2,6 34:11 201:14 communications (1) 18:9 community (1) 109:10 companies (8) 122:15,17,18,20,21 122:23 123:5 275:22 company (2) 81:19 132:5 comparable (1) 216:10 compare (1) 192:17 compared (5) 113:18 225:1 228:5 279:8 283:11 comparing (9) 77:20 108:13 123:24 124:12,18,19 178:3 227:24 304:25 comparison (4) 238:18,19 248:17 314:3 compendium (1) 60:15 compensation (1) 305:6 compilation (1) 197:6 completed (1) 221:20 completely (3) 30:12 82:12 299:14 complicated (1) 131:11 complications (3) 67:24 68:2 215:22 component (5) 30:4,5 97:22 189:9,10 components (4) 53:4,20 97:18 189:21 composition (1) 270:13 comprehensive (5)	53:18 71:9 202:1 213:18 305:14 computation (1) 22:22 computational (1) 278:20 computers (1) 262:22 con- (1) 300:20 concatenating (1) 143:1 concentration (3) 88:23 92:5,14 concept (2) 57:24 201:8 concern (9) 50:1 128:14 130:3 197:16 209:8 224:25 237:15 293:22 304:18 concerned (3) 131:12,14 307:17 concerning (4) 13:23 139:7 218:20 302:24 concerns (3) 142:10,13,20 conclude (7) 19:6 71:22 84:9,14,22 87:3 231:14 concluded (15) 48:7,17 89:18 91:12 91:18 124:15 127:16 129:4,7,8 130:5 181:22 217:16 228:24 289:10 concludes (2) 157:17 309:22 conclusion (16) 28:6 45:8,22 46:8 67:7 75:21,25 93:11 97:23 151:8 157:16 229:4 230:24 279:5 294:4 297:20 conclusions (10) 45:19 46:11 72:21,22 73:3,5,7 75:1 190:7 240:22 concur (1) 277:23 conditions (5) 89:6 91:8 93:3 230:9 283:22 conduct (1)	21:3 conducted (6) 20:15 21:19 24:20 25:10 205:3,3 conducting (1) 22:4 conference (1) 198:1 confidence (2) 79:3,5 confidentiality (2) 138:16 139:10 confirm (2) 6:20 99:4 confirmed (1) 209:22 confirms (1) 204:3 conflict (5) 127:4,10 128:4,16 129:1 conflicts (2) 130:15,20 confounding (2) 225:24 243:13 confuse (1) 9:21 confused (4) 10:2 28:19 59:2 198:11 conglomeration (1) 297:17 connection (11) 8:23 18:18 20:16 28:24 52:22 61:7 135:12 138:5,8 139:6 283:25 connections (1) 272:24 connector (5) 124:8,13,21 128:11 314:5 connectors (3) 124:1,7 129:22 consensus (3) 196:6 198:1 219:21 conservative (1) 235:13 consider (14) 15:14 141:15 142:6 146:4 204:7,10 216:8,18 217:6,7 227:7 238:20 278:15,19 considerable (1) 268:9
--	---	---	--	--

consideration (10) 146:15,21 211:21,24 232:20 267:5 269:12 270:12 271:4 306:20	297:2,7,12	68:17 80:17,18,21 83:14 119:15,25 120:2 137:7 158:21 163:5 175:9 182:3,9 196:1 200:1,10 203:21 209:3 237:3 263:13 264:16 275:21,22 278:3 313:12 314:9,17 315:8	26:19 28:7,8 29:3 29:17,23 30:3,11,23 32:20,21 37:10,12 37:13,16,19,25 38:13,15,17,24,25 41:3 43:21 45:13,24 46:3,19,25 47:1,6 47:20 51:15,18 54:2 54:14,18 57:13,21 60:9,12 61:2 64:7 64:17,21,25 65:7,9 66:19,21,22 73:7,8 73:10 74:4,5,10,22 75:9,12 79:12 81:12 82:7 90:6,7 93:25 94:15 102:6 114:20 123:22,23 124:11 124:14,22,25 125:11 127:1,2,18 128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	correlate (17) 48:8,18 73:16 74:7 79:17,24 82:13 83:16 89:19 90:6,9 90:17 103:15 105:12 109:18 196:18 218:5
considered (22) 24:13,14 27:11 32:4 32:10,19 45:20 49:12 50:14 56:2 59:4 63:4,14 164:21 223:24 224:2 226:4 233:5 238:21 261:3 271:3 304:21	105:23,25 106:1,2 107:7,17 151:14,21 170:23 171:3 180:12 246:7,15 250:21 251:8 303:17,21,25 313:23 315:13	203:21 209:3 237:3 263:13 264:16 275:21,22 278:3 313:12 314:9,17 315:8	41:3 43:21 45:13,24 46:3,19,25 47:1,6 47:20 51:15,18 54:2 54:14,18 57:13,21 60:9,12 61:2 64:7 64:17,21,25 65:7,9 66:19,21,22 73:7,8 73:10 74:4,5,10,22 75:9,12 79:12 81:12 82:7 90:6,7 93:25 94:15 102:6 114:20 123:22,23 124:11 124:14,22,25 125:11 127:1,2,18 128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	105:12 109:18 196:18 218:5
considering (1) 191:5	187:9	62:3,25 107:18 113:4 313:24	66:19,21,22 73:7,8 73:10 74:4,5,10,22 75:9,12 79:12 81:12 82:7 90:6,7 93:25 94:15 102:6 114:20 123:22,23 124:11 124:14,22,25 125:11 127:1,2,18 128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	correlated (8) 49:1 76:1 77:12,18 89:25 91:6 107:9 178:24
consist (1) 103:8	164:15	controlled (5)	64:17,21,25 65:7,9 66:19,21,22 73:7,8 73:10 74:4,5,10,22 75:9,12 79:12 81:12 82:7 90:6,7 93:25 94:15 102:6 114:20 123:22,23 124:11 124:14,22,25 125:11 127:1,2,18 128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	correlates (2) 74:19 91:14
consistency (2) 127:12 129:6	67:19 250:16 268:16	controversy (1) 172:5	125:11 127:1,2,18 128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	correlating (2) 73:22,24
consistent (8) 50:6 62:9 64:14 71:21 72:9,10 92:20 98:23	61:9 313:15	convection (2) 167:4 177:21	128:25 129:13 130:17 132:19 138:3 139:1,15 141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	correlation (22) 49:7 50:8 74:3 77:8 78:1,5,12 79:11,14 80:11 82:11 83:14 84:5,10 86:7,9 91:2 93:16,20 104:3 215:18 303:22
consistently (2) 102:12 120:24	43:23 67:12 88:16 265:12,24 268:25 294:9 300:15	convened (1) 129:3	141:7 143:15,20 147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	corresponded (1) 88:10
constantly (2) 34:9 102:13	context (8) 43:23 67:12 88:16 265:12,24 268:25 294:9 300:15	conversation (3) 11:9 131:19 135:5	147:14 152:18 154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	Cory (1) 75:17
constellation (1) 297:9	continually (1) 116:18	conversations (2) 9:12,14	154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	corynebacterium (1) 255:19
constituted (2) 134:25 194:16	continued (3) 4:1 314:1 315:1	convincing (1) 225:5	154:22,23 156:24 160:1,4 168:2 172:12 182:25 183:1 184:16,17 185:1,2 189:10 191:1 193:11,18 196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	cost (1) 122:11
consult (3) 61:8 122:17 275:20	continuing (2) 215:24 218:18	coolers (2) 34:8 159:18	196:10,11 204:25 205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	COSTA (1) 311:3
consultant (3) 122:14 123:9 278:2	continuous (5) 221:15 228:19,20,22 237:1	coordinating (1) 143:4	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	couldn't/wouldn't (1) 224:16
consulted (2) 122:21,23	CONTRA (1) 311:3	copies (2) 196:21 197:4	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	counsel (17) 4:11 5:17 20:23 21:23 35:14 41:5,15 131:24 132:5,16 133:18 143:11 196:20 279:22 280:7,10,25
consulting (6) 20:8 125:1 275:17,18 276:5 283:19	Contract (1) 54:11	copy (5) 6:21 61:5 157:5 169:17 192:24	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	counsel's (18) 29:11 48:9 113:22 115:5 146:17 168:10 174:22 176:22 189:14,23 208:25 241:13 251:21 260:9 267:14 270:23 274:1 280:17
contact (7) 11:5 12:6 106:11,14 106:15 174:8 272:22	contradict (1) 43:11	corner (1) 249:7	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	count (8) 76:1 83:3 86:7 101:9 114:7 299:20,21 300:23
contacted (3) 12:8,10 242:16	contrary (2) 75:1,6	correct (198) 6:15,16 7:4,5,18 8:25 9:3,4 10:11,19 12:16,20,23 13:9,12 13:17 14:5,8,12,23 15:4,12,18 17:18 18:25 19:5,6,22 22:19,24 23:8 24:19	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	counted (4) 86:20 193:24 194:11
contain (1) 8:16	contrast (3) 101:14 109:15 257:6	correctly (14) 19:18 71:17 87:10 88:5,12,18 89:7,8 112:1 133:3 170:24 217:4 234:9 247:21	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	
contaminate (1) 120:17	contributes (1) 66:8	Corey (21) 4:5 5:19 6:10 9:20 21:12 47:14 69:10 84:24 112:3,9 116:2 146:10 160:7 165:12 180:21 184:10 187:7 194:3 215:24 253:2,7	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	
contaminated (21) 94:22 105:10 106:5 146:25 167:3 197:8 244:22 246:9,13 250:2,9,11 252:2,20 253:16 254:20 294:16 296:19	control (67) 50:20 51:3,10 52:5 54:1,10,16 56:11,13 58:5,12,13,15,24 59:4,9,10,20 60:10 60:11,17 63:9,20 64:4,6,9,15 65:18 65:19,25 66:9 67:1 67:5,6,18,21 68:1,4	correctly (14) 19:18 71:17 87:10 88:5,12,18 89:7,8 112:1 133:3 170:24 217:4 234:9 247:21	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	
		Corrects (1) 15:7	205:1,6,8,12 206:8 206:9,22 207:8 208:14 210:1,18 214:1 215:16,20 217:4,22 220:8 221:22 222:3,7,15 222:23 223:21,25 227:9,14 229:1 231:10 238:14 244:9,16,24 254:23 256:11 257:20 262:10,17,21 266:17 267:10,13 268:4 278:6 280:9 285:6 287:2,18 288:1,17 290:6,12 297:5 301:1,19 307:2	

255:14 counter (1) 83:13 counting (8) 89:5 91:21 92:9 93:2 93:6 95:19 194:1 313:17 country (1) 158:15 counts (33) 46:21,24 48:7,18 50:9 72:4 73:16,16,18,19 74:19 86:2 87:4,6 87:24 88:1 89:20 93:17 95:4,25 96:2 96:4 97:8,15 105:11 105:12 110:5 111:11 114:9,11 147:1 178:17 299:24 counts/microbial (1) 72:6 COUNTY (1) 311:3 couple (12) 17:16 33:14 95:11 123:25 132:20 155:13 166:6 176:4 220:1 228:10 275:12 301:21 court (10) 1:1 5:9,15 6:2 112:4 116:1,3 180:22 302:21 306:20 cover (2) 39:17 53:3 covered (4) 40:2 107:4 179:10 243:12 covers (1) 40:6 CPUs (1) 262:23 Cram (1) 34:4 creates (1) 269:15 credentials (1) 16:4 Creutzfeldt (1) 137:16 Cristina (12) 47:4,11 71:20,21 72:8 72:19 75:2 77:20 101:5 142:3,19 313:8	criteria (9) 35:17 56:14,17,21 68:8 270:9 279:4 308:21 309:6 critical (2) 28:15 230:6 critically (7) 84:20 190:24 191:10 192:9 208:20 305:11 306:11 criticized (1) 133:5 criticizing (5) 133:2,15,23 134:7,25 Cro- (1) 89:9 Croft (1) 89:10 Crossed (1) 35:24 CRR (2) 1:23 311:23 Cryptococcus (1) 255:25 CSR (3) 1:23,24 311:23 cubed (2) 80:7,8 cubic (1) 80:3 Culbertson (1) 154:24 culture (6) 121:25 122:7,25 203:18 222:8 257:25 culture-positive (1) 94:23 cultures (5) 83:8 94:22 185:19 204:3 297:11 culturing (2) 203:22 245:24 Cumulatively (2) 46:20 72:1 curious (4) 85:13 131:5 183:12 198:22 current (7) 7:11 64:22 65:8,14 66:23 68:8 69:21 currently (2) 54:23 135:13 currents (1) 177:21 curriculum (1)	7:8 cut (1) 210:13 <hr/> D D-I-F-F-I-C-I-L-E (...) 120:8 Da-roosh (1) 85:5 Da-veed (3) 85:10,14,19 danger (1) 250:6 dangerous (3) 274:11 302:25 305:16 dangers (1) 141:14 Dar-u-shay (1) 85:1 Darouiche (16) 73:18 74:6 79:15,17 79:24 82:4,24 83:15 83:19 84:9 132:20 133:15,22 134:6 135:3 314:11 Darouiche's (2) 133:6 135:1 dash (1) 197:24 data (64) 25:4 58:20 59:22 60:4 60:4 66:2 71:15 79:1 84:20,21 93:4 93:8 105:14 107:11 109:8 111:7 121:14 126:1,9,9 127:11 128:12,17,20 129:5 130:19,24,25 131:6 134:9 142:24,25 147:6,21 173:13 174:2 178:20 185:18 190:5,6,24 190:25 191:10 192:9 194:3,24 202:8 208:20 229:9 229:23 236:22 240:13 241:9,17,21 286:20 287:3 303:17 304:4,5,5,5 305:7,10 database (1) 149:12 date (9) 34:22 37:23 140:17 140:23 147:22 196:16 200:23	261:10 316:3 date's (1) 261:5 dated (4) 7:2 146:23 199:7 315:15 dates (1) 196:18 David (5) 18:8,11,14,16 85:10 day (27) 13:19,24 14:7 16:16 47:18 100:14 158:15 187:9 218:14,17,24,25 219:1,7,11,17,17,22 221:17 248:22 284:14,19 285:5,7 310:9 311:20 316:23 days (3) 83:8,9,9 DC (1) 11:15 dead (1) 215:8 deal (3) 209:21 265:25 276:18 dealing (1) 159:12 dealt (1) 182:16 debate (1) 172:5 decade (1) 119:19 decades (4) 153:25 159:13 245:6 246:23 December (15) 8:18 15:2 19:13,23 36:12 37:20,24 62:23 63:2 143:16 144:19 260:22 261:12 298:20 315:9 December-ish (1) 144:10 decide (1) 123:18 decided (11) 42:7 49:11 55:13 59:1 62:22 84:2 119:20 121:11 190:21 217:15 245:17 decides (1)	282:7 deciding (2) 52:20,24 decision (4) 52:12 59:19 62:6 130:1 decolonization (3) 171:15,18 195:15 decontaminate (1) 172:9 decrease (3) 81:8 121:16 187:3 decreased (4) 81:1,2 197:17,18 deep (16) 53:12,16,20 81:8 110:18 178:6,22 205:17,22 206:11 206:12 216:22 223:19 224:4 305:21 314:15 defendants (2) 4:3 5:20 defense (2) 133:14 135:1 define (3) 65:17 188:11 263:7 defining (1) 100:24 definitely (6) 26:24 35:1 144:13 172:17 198:25 278:21 definition (4) 50:22 188:13,16 201:7 definitions (1) 190:3 definitively (5) 33:9,12 34:18,25 41:11 degree (4) 153:17 231:25 232:9 306:15 demographics (3) 239:3,6,10 demon- (1) 87:20 demonstrate (2) 111:2 251:19 demonstrated (5) 93:23 94:13 108:24 286:21 297:6 demonstrates (3) 67:19 87:4,24 demonstration (2)
---	--	---	--	---

284:16,18	describe (10)	152:2 190:3	53:10 70:7 110:13	disagree (2)
Denise (1)	10:1 16:10 27:21 62:7	development (17)	113:19 114:3,13,24	117:22 129:15
264:20	78:1 124:10 148:10	20:1 28:17 37:25 38:4	151:10 166:1	disagreed (1)
densities (1)	203:20 244:25	38:19 54:7 55:1,10	207:24 235:17	118:24
80:3	282:16	55:14 56:6 57:16,24	238:16 239:12	disagreement (2)
department (3)	described (10)	60:19 66:24 190:4	240:9,19	46:9 117:25
277:18,22,23	28:12,14 30:18 39:4	274:14 303:11	differences (2)	disagreements (2)
depend (1)	204:15 209:5 212:1	device (46)	52:3 239:5	117:19,20
65:16	245:3 273:7 278:22	80:22 81:13,14,15	different (70)	disclaimer (1)
depended (2)	describing (3)	82:9 86:5 124:2,9	14:18 33:16,17 40:1	264:12
89:20 201:17	43:18 283:5 300:10	137:4 146:24,25	46:18 52:7,18,23	disclose (4)
dependent (1)	description (6)	152:1 159:13 162:1	53:19 54:9,22 55:15	20:10 123:8 127:4,9
276:15	91:7 283:11 293:21	177:18 233:12,24	59:8,11 64:18 73:2	disclosed (1)
depending (4)	303:1 304:2,7	235:15 236:5 245:5	73:3,5,6 75:3 82:12	20:10
122:10 242:24 274:25	design (4)	245:24,25 246:6,22	92:21 100:7 101:16	discontinued (1)
287:12	58:7 100:17,20	249:13 250:4	103:6 104:12 107:1	314:12
depends (10)	258:18	257:13 265:3,8	108:18 112:2 119:8	discovery (1)
21:1 102:19 123:13	designed (1)	266:6,11 268:11,13	124:6 136:12	274:17
151:9 159:9 186:12	62:1	270:13 274:8	137:17 147:7	discuss (3)
204:9 292:10 293:5	despite (2)	275:22 299:22	148:14 152:15	183:3 184:6 244:8
293:8	120:20 315:5	302:25 304:2,7,12	153:15 162:3	discussed (2)
depo (1)	detail (1)	304:24 305:16	186:23 187:10,11	133:18 136:12
301:5	301:6	309:10,10 315:10	197:7 201:18,22,23	discusses (1)
Deponent (2)	detailed (1)	devices (32)	201:25 209:5	244:18
316:4,21	216:23	69:22 104:8,22 106:3	223:14 226:14	discussing (3)
deposited (1)	details (4)	136:6,8,9,10,13	227:25 233:8,19	268:6 281:19 300:15
99:15	28:7 58:7 216:20	182:19 219:13	235:18 238:10,12	discussion (9)
deposition (35)	279:15	235:18 238:17	240:10,15 246:11	85:25 86:1,16 265:25
1:16 2:4 5:6,11 77:3	detect (1)	240:11 246:7,20	260:5 261:5 271:3	268:9,16 274:15
132:10 143:7 145:6	100:15	269:22,24 272:5,6	275:1 290:19 291:6	299:6 309:25
145:8,16 181:15	detected (2)	273:16,18,22	303:13,16,23	discussions (3)
187:11 201:9	88:11 260:14	274:12,21 305:1,21	304:20 305:12,13	22:1 129:23 309:2
202:20 203:13	detecting (1)	307:5,7,8 308:23	different-sized (1)	disease (13)
212:2 216:2,3 239:7	137:16	315:12	89:12	51:10 196:7 214:5,16
244:3 258:21	detection (6)	diabetes (10)	differentially (1)	214:17,17,24 243:6
259:24 260:3 275:5	118:25 119:1,4,6,16	151:24,25 214:17	226:21	263:13 264:16
298:1,16,19,23	122:16	218:1,5 239:14,17	differentiation (1)	275:21 303:9
299:6 301:15	determinants (1)	239:18 242:25	188:17	313:12
309:22 310:2	231:16	243:1	differently (1)	diseases (2)
311:12,13 316:3	determine (6)	diabetic (1)	73:2	278:9,13
depositions (20)	74:3 80:11 104:15	151:22	difficile (4)	dispersal (1)
7:22 33:5 41:19 143:9	126:10 256:22	diagnostic (2)	120:4,7,9,10	247:25
143:17,23,24 145:8	281:22	83:6 216:1	difficult (3)	dispersion (1)
145:10 197:5	determined (1)	diagram (2)	178:16,19 186:20	42:18
198:19,21 199:2	45:21	84:11,17	direct (3)	displacement (2)
200:8 210:25	determining (2)	diameters (1)	61:23 154:15 257:8	124:20 314:5
298:17 304:6 305:2	42:4 83:2	77:21	directed (2)	disruption (1)
306:10 314:20	detriment (1)	diathermy (2)	22:21 137:18	197:12
depth (2)	68:18	101:22 102:8	directly (5)	disseminating (1)
222:21 242:12	devastating (1)	Dickinson (1)	65:10 160:8 250:3	177:16
deputy (3)	232:2	123:3	257:22 259:4	distant (8)
262:8 263:8,23	developed (7)	diff- (1)	director (6)	166:7,15 167:9,12,23
dermal (1)	24:7,16 25:8 55:25	120:6	197:14 262:8 263:8	168:5 169:5 170:3
179:25	56:3,8 274:14	differ (1)	263:18,19,23	distinct (1)
Derouiche (1)	developing (6)	73:6	dirty (1)	24:17
132:25	20:3 23:1 25:1 56:2	difference (15)	203:21	distinction (2)

27:15 51:5 distinguishing (1) 151:17 distribution (1) 79:2 District (4) 1:1,2 5:9,9 division (7) 55:12,17 62:19 262:8 263:8,23 277:14 Dixon (1) 123:3 doctor (11) 21:11 116:6 117:10 218:22 246:25 250:25 251:18 270:15 273:21 306:23 310:1 document (41) 1:7 26:8 48:10 51:1 52:15 72:13 77:13 79:21 132:16 139:20 157:8 169:20 176:24 182:11 197:9 198:14 231:25 259:12 267:15 269:1,7 271:13 301:21 313:2,5,6,10 313:12,15,16,20,23 314:7,12,14,17,22 315:3,8,10,12 documentation (1) 222:5 documentations (1) 61:1 documented (4) 184:14 251:8 252:1 253:16 documenting (6) 66:3 67:22 68:2 197:11,13 250:21 documents (5) 197:3 280:25 281:11 306:3 308:13 doing (50) 39:5,9 40:3 55:16 108:25 120:3,11 121:22 139:11 140:9 178:21 179:16 185:16,16 185:18,21 201:23 201:25 203:18,25 209:18 210:2,3,11 210:12 211:8,12 219:8 228:2,9	231:25 233:8,9,14 233:19,20 234:1,7 236:24,25 245:21 257:7 274:25 276:8 276:16,20 284:17 287:8 291:5 305:6 dollars (1) 25:24 dose (3) 58:21 169:10 220:25 dosing (1) 58:19 dot (2) 295:22 296:14 dots (1) 295:20 doubt (1) 158:11 downgraded (2) 304:10 308:5 downward (1) 249:19 Dr (127) 5:6 6:8 13:14 14:21 15:10,17,19 16:7 17:9,15 18:5,16 22:12,20 23:3 24:18 30:10 31:11,21 43:25 77:4,7 81:5 81:18,21,24 82:4 109:15 115:13 117:19,19,20,25 118:16,18,24 119:8 125:23 127:6 128:4 128:16 129:24 130:13,16 131:18 132:11,14,20,25 133:6,19,22 134:6 135:1,3,5 142:25 143:6 145:16 148:15 150:6 162:18 175:15 177:1 181:16,19 193:14 194:7 195:16,25 201:9 222:22 224:6 225:3 244:4,7 262:7,11,13 262:18 263:5 264:19,20,24 265:1 265:2 266:2 271:2 273:9 274:6 278:22 279:8,15,19,25 280:6,13 281:1,7,14 281:15,16,20,23,24 282:15,21,23 283:4 283:4,12 298:2,6,15	298:16,19 301:16 301:18 302:14 304:25 306:8,12,12 309:23 313:3 314:10,11 draft (5) 61:16 265:3,12 272:16 315:10 drafted (2) 26:24 52:15 drafting (1) 55:4 drafts (1) 61:14 drains (1) 220:19 dramatic (1) 121:16 dramatically (1) 55:8 drape (2) 179:10 180:4 draping (1) 285:18 drawn (1) 230:25 drew (1) 240:22 drill (6) 103:22 104:16 105:6 106:9,19,20 drilling (1) 102:24 drills (7) 101:18 102:23 104:23 105:17 106:7,17 107:8 driven (2) 242:5,6 drop (2) 88:21 314:13 dropped (1) 215:8 drug (2) 169:10 246:19 dry-ability (1) 269:16 Ducky (5) 198:6,14,16 199:16 304:19 ducts (1) 184:20 due (2) 153:4,5 dug (1) 127:8	duly (2) 6:5 311:13 duplication (1) 193:3 duration (11) 109:15 114:7,11 187:1 220:18 221:3 221:6,17,23 222:1 260:13 Duren (1) 198:18 Duren's (1) 198:20 dynamics (2) 22:22 278:20 <hr/> E <hr/> E (2) 3:1,1 e-mail (10) 17:13 132:18,25 135:2 137:10 197:19 198:25 309:2 314:10 315:14 e-mails (3) 17:14 199:14 301:21 earlier (7) 64:2 72:21 86:13 118:9 125:15 162:23 189:8 early (4) 144:11 170:14 219:22 314:15 easier (3) 82:25 188:5 193:5 easy (2) 163:14 203:23 Ed (1) 118:17 Eden (1) 3:13 editor (16) 70:18,21 118:11 125:22 148:15 149:10 279:9,11,18 280:1,21 281:6 282:5,6,6,11 Edmondson (1) 176:2 Edmonson (2) 74:11,16 effect (11) 89:3 91:19 92:25 173:4,5,8,9,10 175:1 254:19	262:14 effective (1) 174:10 efficacy (6) 66:3,4 67:23 68:18 120:22 304:18 efficiency (2) 304:15 307:25 egregious (1) 116:17 either (32) 15:22 23:2 24:17 25:24 29:15 53:8 61:4 67:23 82:21 91:1 107:3,25 117:13,14 121:25 122:24 175:2 185:18 187:3 198:12 199:8 200:7 200:15 204:3 210:24 211:20 212:5 227:7 249:2 250:3 251:8 299:20 electric (2) 101:18 102:5 electrical (1) 289:19 electrocautery (2) 106:10 107:8 electronic (3) 101:8,11 313:16 element (2) 230:6 271:4 elements (3) 269:17,18 271:3 elevated (5) 46:22 72:4 86:3 236:10 238:7 Elghobashi (7) 18:5 22:12,20 24:14 280:6 283:4 306:12 Elghobashi's (10) 23:3 24:18 30:10 31:11,21 278:22 281:24 282:15,21 306:8 eligible (1) 62:5 eliminate (2) 186:6,8 eliminated (3) 185:1 187:21 242:2 eliminating (1) 187:23 emissions (1) 270:5
--	---	---	---	---

emitted (2) 250:18 251:4	111:4	escape (1) 289:12	exactly (9) 40:23 89:16 97:6	33:3,6 36:9 40:17
emitting (1) 294:5	Enterococcus (1) 193:8	escaped (1) 289:11	101:5 137:24	41:9 42:5 46:1,14
emphasize (5) 149:19 150:21 171:4 247:7 249:25	enters (1) 299:25	essential (2) 230:25 286:23	165:14 233:1	47:3,4,7,10,10,12
employed (2) 51:25 66:24	entire (5) 68:15 101:15 102:16 182:3 201:22	essentially (3) 7:10 254:21 262:6	268:20 295:25	51:6,7 52:1 54:7,13
employee (1) 11:18	entities (1) 276:1	estimate (6) 25:14,23 26:2 38:2 40:10,13	EXAMINATION (4) 6:6 302:12 306:24 312:4	57:3,4,6 60:21,22
employing (1) 65:4	entitled (2) 26:9 232:19	et (15) 42:20,20 55:7 71:4,4 73:7 84:9 104:23 107:18 267:6,6 296:18,18 313:8,25	examined (3) 49:2 107:7 283:24	60:24 61:2,4,9,24
enabled (1) 231:14	entrained (1) 256:25	Ethylene (1) 106:17	example (5) 43:24 137:14 245:5 246:21 297:13	86:10,12 107:13,14
encounter (1) 284:21	enumerate (2) 28:6 56:20	etiologic (1) 214:4	excellent (7) 58:20 278:23 279:3,5 281:23 282:16,22	118:4,6 123:19,21
end- (1) 112:25	environment (6) 120:17 155:17 157:7 182:4,18,22	evaluate (4) 84:20 190:24 204:19 303:13	exception (2) 22:12 30:10	125:5,6 126:18,19
ended (3) 218:24 223:4 240:1	environmental (2) 182:16 185:19	evaluated (4) 69:24 70:5 208:20 306:11	excess (1) 167:3	126:21,25 127:19
endemic (3) 156:21 188:18,19	epidemic (3) 188:17 205:25 206:2	evaluating (3) 191:10 192:9 313:17	exchange (1) 17:13	127:23 132:13,15
endocarditis (1) 168:14	epidemiologic (18) 12:9 30:4,7,25 58:13 58:16 59:3,11,22 60:3,4 185:17,18 186:14 188:1 203:16 204:1 231:23	evaluation (7) 57:17,24 126:2 130:13 202:8 214:23 239:21	exchanging (1) 17:14	139:13,16,19,21,23
endogenous (34) 153:8,11 154:20 155:5,14,24,25 156:5,13,14,20 157:12 158:25 163:8 164:1,24 165:3,6,22 166:13 166:17,18 167:17 167:18 169:12 170:20,23 171:12 171:24 176:25 177:24 180:12 186:4 188:20	epidemiological (2) 21:17 204:5	event (2) 188:14 189:2	excited (1) 253:8	140:22 141:8
endpoint (1) 113:1	epidemiologist (3) 11:17 21:7 209:17	events (1) 186:22	exclude (3) 71:13 155:19 204:17	142:14,20 143:22
ends (1) 177:23	epidemiology (5) 12:11 60:14 275:20 275:21 303:9	everybody (2) 160:2 232:5	excluded (6) 57:1 60:5,8 71:12 72:20 306:19	146:1 147:16
energy (1) 198:2	epidermidis (2) 159:24 193:7	evidence (30) 23:23 24:5 30:19 45:9 57:14,20 59:5 68:7 72:13,25 92:12 94:2 103:13 115:1 116:5 116:22 117:4 118:3 126:13 155:12 179:7 180:2 202:14 218:8 243:7 250:10 251:3 290:10 291:20 293:7	excluding (1) 22:3	150:18 153:24
England (7) 148:15,20 149:4,7,8 149:21 201:10	epidermis (2) 160:9 180:25	evolved (1) 55:21	excuse (8) 28:20 47:5 69:14 140:20 184:6 221:16 236:15 249:6	154:14 166:12
enhance (2) 151:13,21	epidermitis (3) 160:3,17 161:1	evolves (1) 62:20	exercise (1) 310:3	169:14,16 170:18
ensued (1) 289:19	equal (6) 48:24,25 77:22 78:7 176:14 178:4	exact (5) 111:13 112:14 131:8 131:10 190:23	exhaust (10) 94:21 184:19,20 246:12,13 248:13 250:3,9 251:10 274:22	180:10 181:21
ensure (1) 183:22	equate (2) 103:11,15		exhausted (1) 245:25	182:5,8,12 192:2,5
entered (1) 45:15	equipment (7) 101:22 106:13 186:16 219:10 262:19 264:16 266:3		exhaustive (2) 262:24 263:4	192:6 199:1,13,19
entering (1)	equivalent (1) 211:4		exhausts (3) 296:19 297:2,7	200:15 204:22,23
	ERRATA (1) 316:1		exhibit (147) 6:17,20 7:6 8:11,14 8:16 15:9 18:22 25:19 26:5,9 27:7 28:2,20,20 32:14	209:8 210:14

166:25 169:13 176:25 177:2,22 181:22 182:19 186:4 expanded (1) 274:20 expect (5) 161:17 202:25 207:19 215:10,22 expected (1) 282:10 expended (1) 25:15 expenses (2) 12:22,25 expensive (2) 178:19 277:2 experience (12) 30:25 49:21 152:24 154:10 160:16 163:22,24 190:1 219:15 263:22 270:4 286:14 experienced (1) 231:4 experiencing (1) 158:23 experiment (3) 23:6 255:9,17 experimental (2) 22:17 24:5 experimentation (1) 260:15 experiments (10) 21:18 23:2,12 31:24 247:25 257:8,11 259:3 299:7,19 expert (32) 6:14,21 7:16 8:2 16:18 19:4 23:7 24:22 25:12 26:14 28:11 32:10 33:5 41:21 51:24 65:2 138:13 140:20,21 143:24 150:10,18 165:7 181:20 244:9 247:1 274:24 275:13 278:16,19 306:19 313:2 expertise (3) 12:11 149:17 303:13 experts (10) 16:16 20:19 22:9 133:1,5,14,22 134:6 135:1 172:22 EXPIRES (1)	316:25 explain (5) 43:22 70:10 124:2 227:18 282:20 explained (1) 270:25 explaining (1) 268:19 exposed (2) 170:22 180:11 exposure (6) 29:16,16 179:18 180:8 222:2 266:20 express (1) 217:6 expressed (2) 138:13 306:4 extensive (3) 25:1 28:15 105:16 extent (10) 11:2 20:7 21:22 52:2 133:17 194:23 201:17 209:16 216:5 283:9 extrapolate (2) 83:16 293:16 extrinsic (1) 106:2 extrinsically (1) 246:8 eyeballing (1) 25:18 eyes (1) 192:22 <hr/> F <hr/> F-U-M-I-G-A-T-U-... 255:24 fact (31) 49:10 53:5 60:17 75:5 82:19 86:2 99:5 109:18 120:21 123:9 158:13 162:7 162:19 164:12 170:9,10 173:11,23 183:10 184:13 206:23 216:17 229:11 230:9 246:17 262:13 268:6 289:11 291:14 294:13 296:5 factor (15) 62:21 152:4 177:7 204:7 208:21 215:12,13 217:15	223:24 227:17 228:17 233:5 237:18 239:25 240:2 factors (43) 59:13 62:5 151:12,19 151:20,20 152:7 153:10 161:24 182:16 185:17 187:2 188:2 210:14 216:14,19 217:8,11 217:13 219:18 222:17,21 223:1,4,7 223:10 227:17,25 228:10,23 229:5,9 229:16 231:2 236:9 238:21 239:13 240:18,20 242:7,12 279:6 314:22 facts (9) 23:23 118:3 126:13 179:7 180:2 202:14 280:17 291:20 293:6 failure (2) 127:4,9 fair (7) 22:14 33:18 49:22 64:1 277:12 284:15 292:2 familiar (3) 23:7 59:6 148:3 fan (5) 106:21 267:9,12 268:2 269:15 fans (1) 262:23 far (4) 175:8 264:3,22 307:17 farms (1) 55:9 fast (2) 122:11 249:15 favor (1) 121:1 favorite (2) 226:25 227:2 FAW (1) 296:19 FAWs (1) 247:2 FDA (13) 34:8,10 135:22,24 136:5,7 137:9,18,22 138:12,23 261:7	308:14 feasible (1) 121:11 February (1) 15:6 federal (1) 52:6 fee (2) 148:7 275:5 feel (1) 181:3 feeling (2) 160:10 202:3 fees (3) 12:25 13:2 25:25 felt (2) 43:15 209:20 female (2) 16:1,2 fever (2) 183:7 221:24 field (18) 94:5 96:4 99:9 111:5 111:16 112:18 147:2 155:18 158:20 177:22 197:10 246:15 247:18 297:17 299:22,25 303:19 315:13 figure (8) 80:6 84:5 86:8 116:16 118:15 213:18 229:12 260:15 figured (2) 279:17 281:3 figures (2) 248:7 249:2 file (8) 5:5 77:3 132:10 134:3 181:15 244:3 298:1 309:22 filed (1) 47:17 filibuster (1) 253:11 filter (29) 94:24,25 95:1 251:9,9 251:15,16 253:18 290:24 293:25 297:15 304:8,9,12 304:14,14,18 307:23,24 308:5,12 308:15,16,17,18,21 308:23 309:4,7 filtered (1)	294:17 filtering (1) 82:5 filters (2) 307:22,24 filtration (7) 82:5 198:8 304:20 307:4,16,25 308:25 final (4) 7:3 15:8 194:24 265:15 finalized (1) 40:8 financed (2) 309:13,16 financial (1) 122:21 find (24) 44:7 45:15 50:7 56:16 78:5 88:19 91:1 105:15,19,21 118:22 130:8 131:3 131:13 190:23 192:21 209:4 217:1 240:25 241:5 247:22 254:13,15 254:17 finding (3) 50:6 91:2 293:17 findings (1) 93:18 fine (7) 82:2 97:12 136:23 181:8 208:2 214:25 243:2 finish (9) 112:7 116:3 146:9 203:9 253:8,13 268:20 269:10 307:20 finished (1) 119:22 fire (2) 232:8 289:19 firm (4) 10:10,17,21 12:15 firms (1) 10:13 first (42) 8:23 9:5,10 11:25 31:25 40:10 57:19 59:8 77:19 86:25 97:22 119:15 120:22 128:8 139:23 140:6 145:24 154:15,16
---	--	---	--	---

154:17 155:10 161:5 192:22 193:1 195:12 199:12,18 217:2,3 218:25 219:1,6,11 220:25 222:13 231:7 241:8 255:8 265:11 266:14 277:10 300:2 First-cut (1) 269:18 Fisher's (2) 131:8,10 fit (2) 113:25 116:8 fitness (2) 214:21 216:21 five (17) 37:11,14 46:18 73:11 80:21 95:11 96:14 98:13 99:18 123:6 140:15 176:6 211:1 257:8,14 275:9 314:18 fixed (1) 220:6 flawed (8) 127:17 128:5,18,21 128:23 129:8 130:5 130:9 flesh (1) 229:19 Fletcher (1) 34:4 float (2) 292:9,21 floor (4) 285:23,24 289:21 290:3 flora (19) 154:20 155:24,25 156:5,13,14,15,20 158:25 164:1 167:5 170:23 171:2,13,24 172:12,13 180:12 188:20 Florida (2) 3:7 15:6 flow (4) 49:4 114:8 197:13 300:1 fluid (4) 22:22 124:20 278:20 314:4 focus (15) 32:2,9 55:23 166:7,15	167:9,12 168:5 169:5 170:3 186:22 192:12 224:19 268:22 270:19 focused (19) 53:7 57:9 58:11 156:4 183:9 224:10 233:14 234:1 240:5 240:6 241:11 242:11 251:25 252:16,25 253:14 254:2,6 257:24 focuses (3) 86:1 136:6 167:23 focusing (2) 33:4 195:2 follicles (4) 172:14 173:12 174:3 179:24 follow (3) 135:9 187:24 266:13 follow-up (1) 274:16 followed (3) 178:22 302:23 303:4 following (2) 97:10 142:16 follows (11) 6:5 48:14 63:12 77:15 79:23 94:11 112:13 169:25 233:18 267:25 274:7 food (3) 144:25 145:1 246:18 force (1) 249:19 forced (10) 1:4 5:7 35:19,22 36:1 69:6 71:1 198:4 299:22 315:12 Forced-air (1) 314:12 forget (1) 180:22 form (108) 23:22 24:23 27:12 29:8 30:14 39:18 40:5 42:9 49:14 50:16 54:24 59:24 66:12 68:10 72:12 72:24 78:15 81:22 82:14 83:23 90:12 92:11 93:13 94:1 95:22 96:24 99:22 100:4,22 103:12,25 104:18 106:24	109:3 111:8,18,21 112:20 114:25 115:3,4 116:17 123:11 125:19 126:12 141:19 142:7,21 146:16 147:17 149:24 151:4,8 152:10 155:11 157:19 159:3 160:21 161:22 162:13 165:10 168:9 172:16 174:19 175:24 176:18,21 178:11 179:6 180:1 186:1,10 189:11 202:13 203:12 204:8 208:24 212:9 212:22 213:6 216:8 223:8 224:18 225:16 228:11 229:21 230:17 232:21 237:19 238:2,23 240:23 259:9,20 263:15 270:22 271:10 272:1,14 273:4,13 282:1 291:19 293:4 294:7 295:24 296:9 303:6 formal (2) 135:21 137:12 former (1) 175:15 formulating (2) 45:20,23 formulation (1) 151:3 forth (6) 118:10,23 226:17,22 302:16 311:12 found (36) 10:25 27:4 45:18 49:18 50:3 69:24 71:6 77:8,12,17 89:25 90:16 91:17 93:20 95:8 105:14 107:9 127:8 131:1 140:3 147:9 164:19 175:13 192:22 207:21 209:22 215:13 219:16 220:1 245:15,20,25 246:4,6 288:8 308:25 foundation (10)	39:19 81:25 159:6 175:25 179:7 212:10 259:10,21 291:20 295:9 four (13) 7:17 53:8 83:9 95:17 140:15 155:8 201:20 205:13 208:16 211:1 213:3 236:24 275:9 fourth (1) 270:6 fraction (1) 48:23 frame (1) 302:15 France (2) 85:16,18 Francisco (6) 1:17 2:6 5:1,12 277:20,22 free (1) 22:1 Freedom (1) 278:4 frequency (1) 188:13 frequent (1) 138:2 friendly (1) 165:17 front (3) 6:23 258:24 264:25 full (10) 61:25 86:16 154:15 154:16,17 217:2,3 282:10 286:19 296:16 fumigatus (3) 255:24 256:3,20 function (2) 183:22,22 functional (1) 248:1 functioning (1) 219:5 funds (1) 277:16 fungal (1) 183:11 further (8) 24:3 146:23 274:15 301:24 306:24 309:18,19 311:15 Furthermore (1) 109:14	future (1) 229:8 <hr/> G <hr/> Gabriel (1) 3:19 Gabrielle (1) 5:25 gap (1) 257:23 garden (1) 159:23 gathered (2) 222:16 229:4 gathering (1) 40:19 Gauthier (2) 301:14,16 gee (3) 46:6 200:12 240:18 general (8) 89:19 136:2 158:18 187:8 216:3 277:20 307:19 308:2 generally (4) 7:24 17:22 53:1 188:12 generate (3) 102:17,23 103:1 generated (3) 39:10 103:22 294:11 generically (1) 123:17 genetic (1) 203:4 genomic (1) 178:23 Georgia (7) 9:2 12:18 127:8 128:13 129:3,20 130:10 getting (9) 69:12 160:19 201:13 213:3 219:12 243:15 249:25 253:8 284:22 giant (1) 294:25 Gillson (4) 199:20 200:21,22,25 give (19) 42:15 56:22 58:23 92:19 130:12 182:8 187:7 202:9 211:21 213:7 214:14 248:7 262:24 263:1,3
--	---	--	--	---

266:9 268:22 269:5 276:17 given (15) 7:16 58:5 109:24 110:6 149:9 169:9 195:25 212:7 230:19 235:18 262:7 270:12 283:8 303:8 311:14 gives (2) 59:8 157:5 giving (1) 151:13 glands (4) 172:15 173:12 174:4 179:24 globally (1) 35:9 gluconate (1) 172:23 go (62) 8:15 13:4 14:24 23:16 28:6 29:14 32:13,22 44:10 53:11,20 58:6 71:16 87:3 89:2 94:25 95:16 96:15 98:14,24 115:25 119:25 131:23 134:9 144:8 146:18 162:23 169:7 170:18 185:11 196:21 198:17 201:4 203:22 211:1 218:22 230:4 231:24 232:6,8 233:3 234:11,22 238:1,5 245:17 250:25 260:17 261:8,10 264:9 266:18 269:21 276:10 277:7,9,16 277:24 280:1 290:17 297:20 301:6 goes (6) 18:14 25:3 62:7 176:11 180:13,16 going (82) 9:21 13:23,24 20:6 21:22 36:4,8 42:7 45:4,14 47:9 53:16 57:3 63:21 65:1 67:9 71:8 75:15 88:13 100:13 101:8 103:5 110:19 112:25 115:22,24	115:25 116:6,10 117:20 118:21 126:17 130:11,12 133:17 135:4,9 146:5 149:12 150:19 152:2 154:3 161:10 174:16 177:4 179:15,19 182:7,8 187:12,15 201:7 209:14,20 213:19 214:18 216:1,4 217:19 218:19 222:20,23 224:20 225:5 226:22 229:14 230:20 236:23 241:1 242:14 243:11 249:12 253:8 254:6 265:9 266:9 268:18 274:11 283:19 294:17 295:11 298:6 gold (14) 28:4,9 30:1 31:3 43:18 44:22 45:5 50:12 51:23 54:22 65:3,3 164:11 185:14 good (14) 5:4 6:8,9 9:25 69:11 69:11 100:20 101:4 173:13 177:13 192:23 204:1,5 243:16 good-looking (1) 9:24 Google (12) 35:15,17 37:2 38:6 39:4 40:3,11,18 44:8 70:24 104:21 303:15 Gordon (608) 3:5 4:5 5:19,19,21,21 6:7,10,18 8:8,12,16 9:17,18,20,20,21,23 9:24 10:4,5,7,9,16 10:21 11:1,9,10 12:14 13:22 14:2 16:22,24 18:10,12 18:13 20:6,14,22 21:5,10,13,21 22:6 23:22 24:2,23 25:5 26:6,7,8 27:12,13 29:8,9,11,18 30:14 30:15,17,20 37:5,6	39:18,21 40:5,7,20 40:24 41:18,20,21 41:22 42:2,9,22 44:17,21 47:8,13,15 47:17,21 48:9,13,20 49:9,14 50:10,16 51:4,8 54:24 55:22 57:2,5 59:24,25 60:2,6,21,23 63:23 64:1,7,10,12,13 66:12,13 67:2,3 68:10,20 69:10,13 69:16 71:11,23,24 72:12,15,16,18,24 73:4 74:15,17 75:8 75:10,15,18 76:4,6 76:22,22,23 77:6 78:3,15,21 79:9 80:9 81:22,23,25 82:3,14,16 83:23 84:8,12,13,15,24 85:2,3,5,6,9,12,13 85:14,17,20 86:11 86:23,24 87:11,13 87:15,17,18,19,21 87:23 88:13,17 89:22 90:4,12,13,15 90:19,20 91:23 92:1 92:7,11,23 93:13,21 94:1,6,16 95:6,22 95:24 96:7,8,10,11 96:24 97:3,5,9 98:10,12,25 99:12 99:19,20,22,25 100:4,19,22 101:1 103:12,16,25 104:5 104:18 105:1 106:24 107:5,12,15 109:3,5,7,22 110:24 111:1,6,12,18,19,21 111:24 112:4,6,10 112:20 113:7,10,11 113:14,16,22 114:12,25 115:3,7,8 115:9,12,13,15,17 115:18,20,22,23 116:2,11,13,15,18 116:21,23 117:1,3,5 117:6,8 118:2,5,7,8 118:14,20 119:22 120:9,23 122:4,13 123:11,20 125:19 126:3,12,17,20 127:20 128:7,19 129:10,14,16 130:2 130:22 131:2,21	132:14 133:16,20 133:24 134:4,8,13 134:17,23,24 135:8 138:24 139:2,17 141:19,24 142:7,12 142:21 143:5 144:21,24 145:1,2 146:8,11,16 147:11 147:17 148:1 149:3 149:24 150:5,14,17 151:4,5,7,16 152:10 152:14 155:11 156:16 157:19 158:8 159:3,4,6,22 160:7,10,15,21 161:14,19,20,22 162:6,13,22 163:2 163:10 165:10,16 168:9,21 169:15,17 169:18,22 170:17 172:16,19 174:19 174:20,22 175:24 176:8,18,19,21 177:25 178:8,9,11 179:1,6,22 180:1,3 180:18,19,25 181:5 181:8,18 182:6 184:9,11 186:1,7,10 186:17 187:5,14 189:11,12,14,18,23 190:10 192:1,3 193:25 194:6,8,12 194:22 195:1 197:1 202:13 203:5,12 204:4,8,21,24 207:25 208:2,6,24 209:6 212:9,17,22 212:23 213:6,12 215:23 216:7 218:18 223:8,15 224:18,24 225:16 225:19 226:7,11 227:3 228:11,13 229:21,25 230:15 230:17,23 232:21 233:2,16 234:3 235:22 236:13 237:19,24 238:2,11 238:23,25 240:23 241:7,13,20 242:21 243:4,15,17,20,23 244:6,11,13 249:21 250:7 251:21 252:3 252:7,10,13,18,21 252:23 253:2,3,7,10 253:12,19,22,24	254:4,8,12 258:3 259:6,7,9,13,20 260:1,9,17,19 261:20,21,23,24 262:1,2,3 263:15,21 266:8 267:14,20,23 268:14,18,21,24 269:2,4,6,9,25 270:22 271:6,10,14 271:22 272:1,7,14 272:19 273:4,8,13 273:20 274:1,3 279:22 280:3,16,23 282:1,14,25 283:13 291:19 292:1 293:4 293:6,10 294:7,19 295:8,16,23 296:6,9 296:12,23,24,25 297:1,19 298:5,25 299:2,4 301:11,24 302:1,4,6,7,8,9,11 302:13 303:6 305:24 306:1,6,13 306:23,25 308:6,8 309:18,19 310:1 312:5,6 gotten (1) 229:7 government (3) 11:18 139:5,7 grade (6) 57:17 58:4 59:3,6,7,8 grades (1) 59:12 grading (4) 57:15,23 58:3 59:7 gram-negative (1) 173:20 gram-positive (1) 173:18 graphic (1) 200:16 great (3) 114:22 181:10 196:23 greater (13) 48:24,25 78:6 88:9,24 92:15 174:15 176:16 178:6 208:10,12 250:1,5 greater/equal (2) 80:5 225:18 grew (4) 255:19,22,25 256:19 grilles (2) 184:19,20 grocery (1)
--	---	--	---	--

285:1	H	236:6,23 275:23	198:8 304:20 307:16	290:24
group (14)	H-U-L-S-E (1)	277:18,22,23	308:12,15 309:4	hollow (1)
51:16 52:13,14 77:12	197:24	279:21 280:14	hereunto (1)	154:21
77:17 114:15,18	hair (4)	healthcare (9)	311:19	honest (1)
120:13 152:25	172:14 173:12 174:3	60:14 104:8,10 137:7	Hey (2)	50:17
202:17 225:20,21	179:24	184:25 187:18	180:21 242:3	honorarium (2)
234:7 277:15	half (3)	262:8 287:4 315:8	HICPAC (7)	12:22,24
groups (1)	138:1 210:21 212:25	healthcare-associat...	137:6 260:22 265:4	honorariums (1)
52:7	Hamer (2)	158:17 287:5	265:14,24 268:10	13:1
grow (1)	143:19 144:3	healthy (1)	273:10	hope (1)
273:24	hand (8)	214:19	high (11)	212:12
growing (1)	56:7 120:12 161:1	hear (2)	201:11 207:6 209:12	hopefully (6)
197:15	184:25 185:6	102:9 234:9	227:18,18 229:13	126:1 177:12 186:5
growth (1)	187:17 286:5	heard (8)	230:13,19 235:21	274:15,20 284:17
114:3	311:20	101:24 102:7 148:5	266:19 304:8	horizontal (2)
guess (33)	handed (2)	149:20 201:3 234:5	high-risk (5)	119:24 120:12
7:7 12:21 18:14 21:1	26:8 132:17	300:2 308:4	121:5,6 266:21 267:4	hose (19)
21:6 23:24 24:9	handful (1)	heat (2)	269:12	252:1,2,17 253:15
33:10 43:2 65:16	108:24	167:3 177:19	higher (18)	254:3,21,25 255:4
70:15 89:24 103:3	hands (2)	heater (2)	58:21 202:6 207:13	255:10 256:6,17
112:8,22 126:14	144:23,25	34:8 159:18	207:15 209:9	257:19,22 258:1
127:24 129:20	hands-on (1)	heater-cooler (14)	214:18 215:15,21	259:5,8,19 272:21
153:9 169:8 176:23	22:4	159:10 162:2 244:8	225:23 226:2,20	297:13
178:13 193:5	Handwritten (2)	244:23 245:2,4,23	229:12 230:12,20	hoses (5)
196:17 201:4,14	314:19,21	249:6,18 256:14	236:1 237:10	268:12 270:10 272:6
204:9 210:10	Hang (1)	263:2 265:25 270:4	242:17 307:15	272:24 297:12
230:19 261:4	21:10	315:4	highest (5)	hospital (20)
263:17 291:8,10	Hannenberg (1)	heater-coolers (1)	58:4 59:12 276:4,7	52:5,9 120:25 121:17
guessing (2)	143:18	266:5	307:25	136:3 160:16
33:1 34:17	Hansen (3)	heater/cooler (2)	highlighting (1)	175:15 188:21
guidance (1)	143:18 144:4 198:18	266:6 274:17	112:9	209:17,18 232:6,24
283:21	happen (2)	heating (1)	highly (1)	235:25 242:16
guideline (58)	20:11 155:8	219:4	242:13	275:21,24 284:11
28:17 50:15,18,19,25	happened (4)	heck (1)	hip (12)	284:21 307:11
51:11,20,21 52:22	17:6 155:20 186:23	9:22	108:19 169:1 206:25	309:11
53:3,6 54:8 55:1,3,5	293:22	heels (1)	207:10,14,15 208:4	hospitals (19)
55:10,10,14,20 56:4	happens (2)	97:10	208:10 209:10	29:14 121:4,11
56:6,7,7,9,12,14,15	168:17 209:2	Heidi (6)	239:11 242:17	142:24,24 147:8
57:7,11 58:17 59:20	happy (5)	1:23 2:7 5:16 181:9	314:16	202:5 205:7 207:1
61:13,14,16,18,22	105:15 130:7 138:18	311:5,23	hip/total (1)	213:20 226:14,16
62:12,14,20,24 63:5	150:3 232:25	held (3)	71:3	226:23 229:14
63:15 65:6,8,15	Harbarth (1)	2:5 5:11 309:25	hips (8)	275:24 277:5,6
68:14,16 155:4,21	118:17	help (6)	207:7 208:16,23	278:1 313:22
155:22 165:21,24	harbors (1)	19:11 57:3 137:2	210:2,7 211:4,8	host (1)
165:25 170:19	108:21	180:9 242:4,20	213:3	152:3
176:24 303:11	hard (2)	helped (1)	hired (2)	HotDog (16)
313:10,13	61:5 193:2	209:22	6:12 237:2	108:13 111:3,17
guidelines (18)	hard-pressed (1)	helpful (1)	Hmm (1)	112:19 113:19,21
45:7 51:18 54:21 56:3	123:15	149:11	85:17	193:6,9,10,16 195:7
56:18,22 60:20	HCU's (3)	helps (1)	HODGES (1)	233:7 236:15,16
62:18,19 64:20,23	247:2,5 260:17	192:1	3:18	299:10 305:8
66:25 68:9 153:23	head (2)	hematocrit (1)	hold (1)	HotDog-only (2)
157:14 164:21	113:18,19	217:21	306:14	192:18 195:4
166:12 181:21	health (15)	hematogenous (1)	hole (2)	hour (10)
guilty (1)	104:8,10 135:16	168:15	295:15 296:3	110:16 274:23 275:3
160:10	201:9,14,15 214:15	HEPA (6)	holes (1)	275:3,4 276:10,14

276:19,21 302:1 hourly (1) 276:13 hours (15) 20:1 22:25 24:8 37:8 37:12,14,18,21 38:3 38:16,18,22 39:1,25 275:10 housekeeping (3) 8:9 219:8,11 Houston (1) 3:21 HPA (2) 201:15 236:17 huge (3) 44:3 56:22 212:8 Hugger (146) 1:4 5:7 6:14 8:24 11:8 11:21 12:4 14:22 15:10,13,15 18:19 18:23 19:25 20:5,16 20:20 21:19 24:7,16 24:21 25:4 28:24 29:17 30:6 35:24 36:1 65:12 66:4,7 66:17 67:7,12,19,23 68:3,5,18 70:25 93:23 94:4,13 95:9 96:3,23 97:7,24 99:8,8,14,16 101:15 102:13 104:4 105:7 105:8,9,10 106:4 108:13,21 109:25 111:3,15 112:17 113:18,21 138:5,9 138:14,20 139:9 141:14 146:24 147:10 151:2,2,15 159:12 167:2 177:19 190:17 195:6 197:8,11,12 197:17 198:8 202:10 233:6 236:15,16,20 245:1 246:11,14 247:1 248:12,18 249:1,6,8 249:11 250:2,9,11 250:18,22 251:5,10 251:15,20 253:5 255:19 259:19 266:21 270:10 272:22 283:14,25 289:11,12,18,23 290:25 291:15 294:5,12 296:19 297:7,16 299:9,11	300:25 302:25 303:14,17,20 304:2 304:6,24 305:1,9,16 308:25 309:8 Hugger-only (5) 192:16 193:22 194:14 194:17 195:4 Hugger/HotDog (1) 200:4 Huggers (5) 255:9 257:7 266:16 303:18,20 huh (1) 289:21 Hulse-Stevens (1) 197:21 Hummel (1) 154:24 hunch (1) 222:22 hundred (1) 100:15 hundreds (1) 121:8 HVAC (2) 183:21 184:1 hygiene (2) 56:7 120:13 hypothermia (4) 35:24 36:1 53:13 71:1 hypothesis (10) 229:15 233:11,22 235:15,19 237:16 238:8,15 241:16 293:24 <hr/> I <hr/> I-O-B-A-N (1) 179:13 ICU (1) 128:9 idea (13) 57:22 83:22 85:2 119:24 129:19,23 209:19 232:4 265:11 280:18 282:19 293:11 294:22 identified (10) 41:10 47:4 120:15 201:10 205:10 210:15 216:21 228:9,17 245:23 identifies (1) 204:2 identify (14)	15:1 32:22 33:6 57:6 62:2 121:4,6 131:24 149:5 161:10 188:1 203:25 234:10 252:4 identifying (2) 186:14 231:24 identity (1) 221:12 ignore (1) 44:11 ignored (1) 63:2 ignores (2) 44:3 116:19 ignoring (3) 115:2 177:1 259:16 illness (2) 215:4 231:15 illustrates (1) 296:2 immediate (5) 173:4,5,8,9 175:1 immediately (1) 83:13 immunity (1) 152:4 impact (22) 53:15 80:24 104:7 109:16 170:15 171:21,23 172:11 174:6 195:8,12 196:2 197:12 212:8 223:19 224:4,16 228:1 229:17 232:2 269:20 303:19 impacted (2) 226:21 240:21 impacting (1) 235:16 impacts (1) 141:9 impetus (1) 238:6 implant (18) 101:12,17 102:11 107:10 108:17 109:2,11,13,20 110:2,9,12,14 167:25 172:2 174:14 179:5 210:6 implanted (2) 167:25 220:3 implants (3) 110:18 168:7 305:18 implemented (3)	200:2,11 304:21 implicated (1) 246:21 importance (5) 155:24 171:4,7 184:1 269:22 important (18) 51:4 125:12 165:23 168:25 172:4 177:7 177:23 212:12 216:22 218:25 219:18 224:23 243:6 270:9 279:17 282:9 287:9 301:3 improvement (3) 156:3,6,7 in-house (1) 4:11 In-person (1) 17:10 in-use (1) 309:10 inactivated (2) 173:21 174:9 inadequate (1) 94:24 inches (5) 256:12,17,23 257:1 257:18 incidence (1) 124:4 incidental (1) 284:21 incised (3) 170:22 175:22 180:11 incision (5) 46:23 178:5 179:4,16 221:1 incisional (1) 81:3 include (14) 27:9 36:20 38:1 42:5 42:7 43:10 49:11 54:15 59:20 96:5 155:16 250:22 262:22 303:1 included (22) 25:1 30:2,6,7 36:15 37:1 44:23 47:11 56:25 59:22 62:3 63:7,18 71:14 206:7 261:4 269:17,19 279:6 282:11 283:6 283:6 includes (7) 26:16 30:1,4,24 197:7	267:5 269:12 including (6) 24:5 221:17 246:3 251:13 287:6 304:20 inclusion (6) 56:14,17,21 62:5 190:22 270:2 inclusive (1) 65:7 income (1) 275:11 inconsistent (1) 72:22 incontinence (1) 216:20 incorporate (1) 198:7 incorporated (2) 5:14 190:6 increase (30) 46:23,24 72:6,6 95:8 95:14,20,25 96:2 97:15 101:10 105:11 110:1,4 111:16 112:17 147:9 151:23 152:7 153:11 187:3 197:10 198:5 206:24 210:16 240:15 299:20,23 304:23 315:12 increased (22) 93:23 94:14 95:3 97:8 97:24 99:6,10 100:2 114:7,9,11 122:22 152:1 189:4 198:4 215:14 219:7 231:3 233:13,24 237:22 303:18 increases (8) 69:6 94:5 96:4,23 104:16 109:20 147:1 297:16 independent (4) 29:6 41:14 129:7 130:5 independently (1) 82:8 INDEX (4) 312:1 313:1 314:1 315:1 indicate (1) 114:6 indicated (1) 45:25
--	---	---	--	---

<p>indicating (2) 54:5 91:11</p> <p>indication (4) 87:6 88:2 217:5,7</p> <p>individual (13) 186:12,18,21 187:2 191:11 209:13 231:24 241:24 275:25 288:9 289:8 292:3,8</p> <p>individualized (1) 242:8</p> <p>individually (1) 291:22</p> <p>individuals (1) 292:22</p> <p>infected (4) 120:18 121:7 213:3 249:25</p> <p>infecting (1) 160:24</p> <p>infection (123) 23:20 52:5 53:4,13 54:21 56:18 57:11 60:17 63:4 64:19,23 65:6,15 66:25 67:24 68:9,16 80:25 99:11 103:6 104:3 105:5 105:20 109:11,18 109:21 110:9,11,21 112:23 114:21 119:15,24 120:2,14 137:7 150:23,23 151:3,13 152:2 153:2 156:3 157:9 158:5,10,21 159:15 159:25 160:17 162:4 163:5 166:8 166:15 167:9,13,23 168:6,19 169:5,11 170:4 171:21 178:7 182:3,9 184:2 187:3 188:2,22 191:11,14 193:15 197:16 198:5 200:1,10 201:11 203:10,21 205:22 206:12,25 208:9,11 211:16 212:13 213:9 216:22 218:9 222:6 223:19 224:17 228:5 229:18 230:13 231:4,17 232:5,11 233:13,25 235:16,17 236:1,11 237:3,23 238:7,10</p>	<p>238:13 240:10,15 245:10 275:21,22 313:11,13 314:4,9 314:13,17 315:8</p> <p>infections (120) 8:1 35:19,20,23,23,25 51:12 52:9 65:12,21 66:2,5,6,8,18 67:8 67:10,14 68:3,5,19 71:2,3 81:9 86:2 104:11,17,24 107:9 108:19 110:20 113:2 114:6,16,22 119:18 121:2,10,16 124:5 147:3,4,10 156:21 158:14,18 158:24 159:16,19 159:24 161:17 162:10,18 166:1 170:14,14 171:9,12 171:12,24 178:23 181:25 183:11,16 185:24 188:18,19 188:23 190:18 191:7 193:7,11,12 193:23 194:14,17 196:13 198:3 202:9 202:25 204:6,14,16 205:4,10,16,17 206:11 207:7,10,10 208:23 210:16 212:8 215:19 217:12 224:5 227:19 230:4 234:11,16 235:1,4 235:21 236:8 237:10 241:3 243:7 246:16 283:21 287:6,6,7,11 292:16 305:17,20,22 314:15,22</p> <p>infectious (6) 183:3 196:7 275:20 278:8,13 303:9</p> <p>influence (2) 82:2 111:11</p> <p>influenced (1) 62:6</p> <p>influenza (1) 183:6</p> <p>inform (4) 24:22 25:9,11 286:11</p> <p>information (24) 11:3 20:9 24:1 27:1 133:18 134:1 141:13 143:1 147:6</p>	<p>193:3 200:1 216:1 222:17,25 227:15 229:5,8 241:25 278:4 279:14 281:3 281:15 286:25 294:15</p> <p>informed (2) 24:8 32:10</p> <p>infrequently (1) 276:25</p> <p>infusion (1) 137:15</p> <p>initial (3) 26:17 62:1 308:11</p> <p>initially (4) 10:10 209:22 245:7 308:12</p> <p>initiated (1) 125:23</p> <p>innocuous (1) 224:13</p> <p>inquiry (3) 13:23 215:25 218:20</p> <p>insertion (1) 175:12</p> <p>Inside (1) 102:21</p> <p>installation (1) 183:20</p> <p>instance (14) 31:11 36:17 50:25 56:7 58:17 121:14 137:15 156:6 159:9 161:2,4 199:12 264:8 272:21</p> <p>Institutes (3) 135:16 279:21 280:14</p> <p>instruct (3) 21:24 134:19 135:7</p> <p>instructing (1) 20:24</p> <p>instruction (1) 135:9</p> <p>instructions (2) 269:14,24</p> <p>instruments (1) 155:17</p> <p>insulin (4) 137:15 218:4 242:25 243:3</p> <p>intake (3) 94:21,23 254:2</p> <p>integrity (1) 147:16</p> <p>intend (1) 14:3</p>	<p>intensity (1) 201:24</p> <p>intensive (3) 42:18 236:19,25</p> <p>interdisciplinary (1) 129:2</p> <p>interest (9) 27:23 122:22 127:5 127:10 128:4,16 129:1 130:16,20</p> <p>interested (5) 11:7 12:12 85:24 225:9 311:17</p> <p>interesting (2) 62:21 245:13</p> <p>interface (24) 266:25 267:5,8,13 268:3,7,8,17,23 269:8,13,14 270:19 271:8 272:8,10,20 272:23 273:1,3,3,11 273:22 274:10</p> <p>interfaced (1) 267:7</p> <p>intermediary (3) 11:6,11,22</p> <p>intermediate (2) 161:6,8</p> <p>intermittently (1) 102:14</p> <p>internal (1) 259:17</p> <p>international (1) 197:25</p> <p>internet (1) 304:3</p> <p>internist (1) 214:23</p> <p>interpose (1) 187:6</p> <p>interpret (2) 91:11 270:24</p> <p>interpretation (10) 83:19 84:11,17 269:5 270:25 271:20 272:16 273:2 274:5 282:12</p> <p>interpreted (1) 269:4</p> <p>interrupt (2) 198:10 215:24</p> <p>interrupting (3) 252:22 253:13 269:9</p> <p>interruption (3) 50:23 115:11,19</p> <p>interval (2)</p>	<p>79:3,6</p> <p>interventions (4) 120:13 155:23 186:24 195:5</p> <p>interview (1) 227:12</p> <p>intraoperative (3) 220:16 221:7 299:23</p> <p>intravenous (2) 124:1 314:5</p> <p>intrinsic (3) 59:14 106:1 246:7</p> <p>introduce (1) 5:17</p> <p>investigate (5) 158:19 162:11 186:9 227:8,11</p> <p>investigated (13) 153:1,3 154:12 158:3 161:9,13 162:4,5,20 185:1 187:21 218:24 219:25</p> <p>investigates (1) 161:16</p> <p>investigating (5) 105:3 162:21 163:22 187:22 219:16</p> <p>investigation (33) 28:13 29:7 30:3 127:17 130:15,18 152:25 159:2,10 160:20,25 185:11 188:7 204:1 205:4 207:6 222:18 233:10,15,21 234:2 234:8,12 237:14 242:8 244:18,19 245:22 276:20,22 277:8,12,21</p> <p>investigations (12) 28:21,23 29:21 30:2 45:7 162:8 190:3 203:15 204:11 246:4 274:16 303:11</p> <p>investigator (1) 162:9</p> <p>investigators (1) 308:22</p> <p>invoice (11) 8:23 9:1 12:17 13:18 14:20 15:8 16:8 19:2,12 36:13,15</p> <p>invoices (12) 8:14,17 12:21 14:25 16:8 18:21 19:7</p>
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25:16,18 36:8 39:22 313:4 involve (6) 95:15 96:14 97:15 98:5,8 109:2 involved (12) 10:14 14:15 15:14 28:16 38:19,20 96:18 98:21 99:17 130:16,21 210:22 involvement (1) 11:20 involves (1) 28:13 involving (3) 6:14 68:5 160:17 Ioban (3) 179:10,13 180:4 iodine (17) 156:8,11 172:8 173:15,17,19,21 174:1,7,10,15,24,25 175:3,4,10,16 iodine-impregnated... 179:15 irregularly (1) 137:20 irrelevant (2) 249:20,24 irrigations (1) 220:16 is- (1) 118:25 isolation (6) 118:25 119:1,4,6,16 121:8 Israel (1) 85:15 issue (14) 58:23 65:11 73:15 168:5 176:10 198:2 202:11,16 212:19 222:24 229:16 242:9 268:23,23 issued (3) 46:5,7 306:4 issues (11) 23:20 122:12 137:9 138:4 139:8 197:8 216:6 219:4 267:6 269:13 305:13 issuing (1) 41:12 Italy (3) 47:14,16 49:23 items (4)	19:24 139:12 269:15 269:19 IV (1) 219:10 <hr/> J <hr/> Jakob (1) 137:16 JAMA (1) 118:11 Janine (1) 13:14 January (5) 140:11,20 144:11 206:3,4 Jarvis (33) 1:16 2:5 5:6 6:4,8,20 13:7,10 26:9 71:17 77:4,7 115:13 132:11,14 133:19 135:5 181:16,19 192:5 244:4,7 298:2 298:6,7 302:14 309:23 310:7 311:11 312:2 313:3 313:5 314:11 Jason (4) 13:7,10,13,14 JNE/FLN (2) 1:6 5:10 JOB (1) 1:25 jog (2) 35:4 118:12 joined (1) 97:20 joint (60) 35:23 65:20 66:2,5,8 66:18 67:14,24,25 68:3,4,19 69:22 71:2 101:17 104:11 105:20 108:19 110:20,21 147:4,9 166:1,24 171:21 175:22 176:16 177:4 178:6,22,23 179:5 183:16 185:24 190:18 196:3,5 198:3 202:25 204:6 205:17,22 206:11 206:12 207:7 212:8 214:4 215:19 223:19 224:4,17 236:7,11 287:7,11 292:16 305:18,21	305:21 314:13 joints (2) 166:3 184:3 journal (26) 42:11 70:21 125:7,22 127:1,21 147:6,20 147:24 148:4,15,16 148:20,23 149:4,7,8 149:11,21 150:2 156:25 157:4,15 158:1 282:5 314:9 journal's (1) 147:23 journals (3) 148:24 150:3 308:22 judge (2) 43:13 116:14 Julie (1) 199:20 July (6) 1:18 2:1 5:2,13 14:11 301:21 jump (3) 88:7 179:20,20 jumping (1) 177:8 June (1) 244:14 jurisdiction (1) 137:3 jury (2) 302:21 306:20 <hr/> K <hr/> K-I-R-K-S-E-Y (1) 33:22 K-O-E-N-I-G-S-H... 16:22 K-U-H-M-E (1) 34:2 keep (2) 6:23 278:1 KENNEDY (1) 3:18 key (1) 104:21 kill (2) 180:4,6 killed (1) 177:13 kind (36) 20:4 25:3,10,18 55:21 56:23 63:10 70:2 83:3 141:12 142:16 143:3 157:15 158:11 175:6 176:2	186:22 188:24 195:15 197:6 199:17 202:5,18,19 214:15 215:3 219:12 236:4,4,9,21 257:23 259:23 260:14 275:18 291:22 Kirksey (2) 33:19,22 knee (23) 71:3 108:17,20 205:5 205:23 207:10,13 207:15 208:11,12 209:9 210:16 214:7 220:2,3 222:12 227:18 229:13 231:16 239:11 242:3,17 314:23 knees (11) 206:21 207:7 208:5 208:15,23 209:12 210:3,3,7 211:4 213:4 knew (7) 31:23 199:16 222:23 232:1 243:10 284:17 301:4 know (173) 10:1,24 11:20 16:3 19:11 20:22 21:2,23 21:25 23:14 32:25 32:25 33:7,11 35:1 35:6 40:22 41:12 43:13 48:2 50:4 53:2 56:20 68:25 81:18 82:18 83:9 87:16,21 95:2,11 99:2,7 100:23 103:14,18 105:14 105:24 106:5 107:1 108:23 110:17 117:10 119:25 123:4 125:21,21,24 126:22,22,24 128:6 128:9,12,13 129:21 129:22 131:1,7 133:13 134:5,10 136:11,25 137:4 138:15 140:2,4,10 140:22 141:11 142:4,17 143:25 145:19 146:3 147:19 149:14 150:6,10,16,16 151:13 153:18	157:21,22 162:21 173:13 175:8 176:6 178:20 183:13 185:16 187:25 190:2 193:19,21,24 194:2,4,23 195:11 196:20 200:12,14 201:25 202:15 203:1,3 204:14 205:20 208:1 209:2 209:14 211:11,12 211:23 213:2,11 214:22 215:17 216:11 224:6,7,8,13 226:3 229:20 231:19 234:23 235:8 236:2 237:13 239:8 242:25 243:1 243:7 246:23 248:15 250:25 251:10 253:7 255:16 257:14 259:10 260:12 262:11 263:7 264:3 268:12 270:10,14 270:16 272:23,25 279:25 280:20,22 282:17 284:1 288:6 289:4,9 290:1,22 291:24 292:23 294:8,13,24 298:22 306:8 309:16 knowing (2) 190:5 206:11 knowledge (4) 128:3 211:9 259:16 303:12 known (1) 162:1 knows (2) 120:16 292:24 Koenigsberg (1) 16:20 Koenigshofer (4) 16:23 17:2 144:15,17 Kuhme (2) 33:24 34:1 Kurtz (1) 144:3 Kurz (1) 305:3 <hr/> L <hr/> LA (1) 15:10 lab (1)
---	---	---	--	--

21:17 laboratory (7) 30:5,7 203:17,23,24 204:2 304:13 lack (9) 39:18 159:6 175:24 179:7 212:9 259:9 259:20 291:19 295:8 Lacks (1) 81:25 lag (1) 222:4 Lague (1) 96:5 laminar (5) 49:4 114:8 197:13 299:25 303:20 Lampotang (1) 144:4 Lancet (2) 148:16,21 land (1) 306:21 large (6) 52:2 55:1 113:3 232:13,15 234:15 larger (4) 113:2 291:17,24 296:5 laser (1) 83:12 late (3) 170:14 248:21 314:15 latest-in-time (1) 315:14 latitude (1) 187:7 laudable (1) 270:3 laughter (2) 85:11 302:3 law (9) 3:5,12,19 4:5 10:9,13 10:17,21 284:11 lawsuit (2) 66:16 67:11 lawsuits (3) 7:16 243:18 275:13 lawyer (4) 11:11 15:15 18:19 26:7 lawyers (3) 12:14,15 14:14 layer (1) 172:9	layers (1) 179:25 lead (5) 120:17 160:25 197:18 219:3 274:15 leadership (1) 129:3 leading (1) 305:24 leads (1) 305:15 leak (1) 224:7 Leaper (4) 33:13 96:5 250:23,23 learn (1) 32:3 learned (4) 155:10 193:1,2 200:9 leave (2) 100:12,14 leaving (1) 224:14 led (5) 45:9 234:11 245:20 246:14 274:16 left (5) 22:14 85:4 87:11 266:24 267:9 left-hand (3) 231:7 247:13 248:2 legal (2) 5:15 151:7 Legg (1) 145:15 Legg's (1) 145:16 Legionnaires (1) 183:7 length (3) 239:14,17,18 let's (34) 8:21 32:13 33:3 36:21 36:23,23 57:2 67:5 71:19 112:10 117:10 150:18,19 152:15 159:24 166:4 168:19 170:18 172:6 182:21 192:12 195:14 196:21 213:16 233:3 237:23 247:10 260:17 261:15,18 264:24 285:3 292:19 297:19	letter (8) 118:11,17 279:9,10 279:18 280:21 281:6 282:11 letters (4) 118:10 280:1 282:4,5 level (4) 83:3 277:14,14,15 levels (3) 88:23 92:5,14 LEVIN (1) 3:3 liability (3) 1:5 5:8 8:5 LICENSE (1) 1:24 Lidwell (4) 33:13 74:11,14,15 Lidwells (1) 33:15 lifted (1) 139:11 ligament (1) 110:17 likelihood (3) 151:13,21,23 limb (1) 221:7 limit (3) 21:7 56:10 62:6 limitations (2) 49:6,10 limited (15) 48:22 57:8 63:6,16 64:3,21,24 65:25 101:14 114:2,4,14 254:15 283:9 306:19 limiting (2) 64:3 66:25 limits (1) 274:10 line (9) 185:16 187:25 191:24 215:25 242:5 245:14 266:24 291:22 303:4 line-associated (3) 123:25 124:5 314:3 lined (1) 193:5 lines (2) 94:23 231:9 link (3) 71:7 203:6 244:22 linked (1)	226:1 links (1) 270:14 liquid (1) 257:25 list (28) 7:15 26:14 32:17 33:3 47:2 68:21 107:24 107:25 108:1 117:13 133:7 146:3 146:20,20 157:5 162:2 183:2 191:24 198:13,13,21 203:1 262:24 263:1,4 281:10 298:17,22 listed (10) 27:17,18 33:6 42:5 46:1 143:17,23 258:11 261:2 298:19 listing (3) 188:1 197:7 242:6 listings (1) 185:16 lists (2) 145:15,18 literally (6) 121:8 179:17 210:18 212:15 245:6,11 literature (57) 22:4 25:2 28:16 29:2 30:6,13 31:5,7,12 31:20 35:15 36:12 36:16 37:1,21 38:5 38:20,22 40:4 44:4 44:20,24 52:11,14 52:20,21,25 54:9,16 55:20,23 56:2,5 61:25 62:6 63:3,13 68:8 69:4,21 146:5 154:6,13 156:18 162:24 163:7 164:17 204:13 224:21,21 242:6 245:8,9 288:2,8 303:2 306:9 litigation (15) 1:5 5:8 6:11,13 8:24 9:6 10:14,18 11:21 18:23 20:21 28:24 280:8,11 283:25 little (22) 28:19 34:24 52:19 59:2,18 71:7 152:13 155:21 160:12 175:6 186:20 188:6	189:8 198:11 205:11 207:23 230:7 262:23 283:3 295:11,20 302:5 live (1) 229:20 LiveNote (2) 2:11 311:8 LLC (2) 13:8,11 load (4) 49:1 50:5 230:11 313:7 local (1) 299:24 localized (1) 82:5 located (1) 249:9 location (1) 153:18 logistic (1) 231:11 lonesome (1) 292:9 long (14) 19:23 63:11 85:7 136:2,16,18 140:6 144:5 188:22 234:25 257:13 286:7,8,8 long-term (3) 173:5,9,10 longer (6) 109:19 114:7,11 120:15 159:20 174:6 look (127) 23:16 33:2 35:1,3,4,8 35:8 44:7 47:23 49:18 50:19,22 51:2 52:10,11 53:25 60:13,16,17 69:8 70:9 71:17 75:16 79:1,2,2,4 80:15,16 80:16 84:19 89:16 95:16 96:15 97:18 98:14,19 99:3 105:16 106:25 111:7,24 113:1 115:14 116:6 121:14,17 127:21 137:12 148:2 150:18 155:20 166:4 168:11 169:24 174:24
---	--	--	---	--

182:1 185:17 186:21 187:15 188:21 189:2,25 190:6,23 191:6,11 191:19,20,22 192:15 196:15 198:17,23 199:4 202:6 204:13,16 207:13,16 208:1,19 211:2,12,13,15,15 211:25,25 213:8,14 213:16 215:7,9 218:17 219:18,20 223:11,22 224:15 226:10 235:9 239:3 240:25 241:5,8,12 242:4 243:3 245:18 247:10 254:11 264:8 271:18 275:9 278:25 281:17 285:25 288:21 289:9,10 290:14,17 291:5,11 305:11 309:15 looked (90) 27:2 31:14,18 35:7 48:24 49:7 50:2 54:8 73:17,18,19 77:20 80:2 89:11,14 89:14 94:19 95:5,8 95:12 99:14 104:6 104:14 105:24 128:17,20 129:4 137:14,15 148:5 153:14 160:8 163:13 190:8 191:17,24 205:7,9 211:11,17 213:25 217:19,20,23 218:1 218:4,8,11,14 219:18 220:2,9,12 220:15,18,21,24 221:3,6,10,12,15,23 222:1,4,8,11,16 223:3,13,17,25 225:1,25 226:3 228:4 229:16 240:17 242:20 255:9 260:25 287:23 288:2 290:18,20 304:4 306:8,9,10,11 looking (56) 7:15 9:25 25:3 26:14 36:3,4 50:8 53:19 58:12 80:22 82:19	83:7,20 85:6 95:2,3 100:6,11 105:17,17 105:17 108:15 124:4 125:25 130:20 147:21,22 153:17 157:24 170:7,13 175:2,16 185:19 186:23 191:10 192:8 194:1 198:7,14,15 204:6 208:7 222:21 223:7 226:4 232:9 240:7,8 243:9 279:6 286:1 302:24 304:17,22 305:2 looks (12) 6:22 15:2 25:19 78:6 132:17 147:8 192:7 197:4 258:25 268:5 282:7 308:14 Los (1) 14:21 lot (18) 54:8 110:13 156:13 159:20 176:3 177:14 187:2 188:18 194:18 203:2,19 211:8 222:25 229:10 243:8 256:13 293:3 302:14 lots (1) 215:19 Louisiana (1) 3:14 love (2) 47:15 138:16 lower (4) 110:7 179:25 285:15 308:25 lowest (1) 59:12 lunch (1) 131:21 lung (1) 214:17 M M-O-R-D-E- (1) 132:2 M-O-R-D-E-C-A-I ... 132:4 M-U-P-I-R-O-C-I-... 171:19 195:23 M.D (6) 1:16 2:5 6:4 310:7	311:11 312:2 machine (3) 221:16 254:2 294:12 magnifier (1) 192:25 magnitude (1) 248:16 Maharaj (2) 143:18 144:4 maintain (1) 53:14 maintenance (3) 128:14 183:21 270:8 major (1) 239:25 majority (16) 41:1,16,25 107:3 154:5 156:19 157:2 157:11,18 158:14 162:25 163:18 181:23 194:16 195:3 251:24 making (5) 27:22 42:24 43:1 126:1 297:14 Male (1) 16:1 malpractice (2) 8:6,7 management (1) 55:12 mandated (2) 236:7,23 mandating (1) 236:18 manner (1) 299:23 manufacture (3) 122:15 246:8,9 manufacturer (2) 128:11 269:23 manufacturers (2) 246:5,20 manufacturing (1) 246:5 manuscript (1) 69:20 March (31) 7:4,12,20 8:18,19 15:5,9,11 18:23 19:2,4,8,8 25:22 32:5,11,19,23 33:8 35:2,7 38:8,11 39:16,23 40:8,9 43:9 140:21 141:3 298:24	mark (3) 118:13 196:22 261:24 marked (46) 6:17,19 8:11,14 18:21 26:5,8 47:7,9 51:7 57:4 60:22 86:10 107:14 118:4 123:19,21 125:4 126:19,25 127:19 132:13,15 139:16 139:18 169:14 182:5 192:2,4,5 196:25 204:23 244:12 258:2,4,5,20 260:18,20 266:7 298:4,7,10 301:10 301:12,13 Market (2) 2:5 5:11 marketing (1) 150:11 marking (1) 51:6 marks (6) 77:2 132:9 181:14 244:2 297:25 309:21 marriage (1) 311:17 material (9) 21:2 60:25 61:12,20 141:10,16 173:22 173:24 174:8 materials (45) 11:7 12:3 15:3 19:13 19:15,19 26:9,16,20 26:21 27:18 32:14 32:16 35:11,13 39:6 41:5,9 42:4,14 43:9 47:3,12 68:22 108:1 117:15 134:9 137:11 139:13,21 142:4 143:21 146:3 150:11 155:17 198:13 216:12 258:12 261:3 270:13 275:2 281:11 294:10 298:22 313:5 math (2) 38:15,25 matter (7) 5:7 10:10 11:24 95:14 231:21 243:11 311:18 matters (3)	35:5,10 243:19 McGovern (38) 96:5,17,18 97:17,22 97:23 144:6,7,9,18 145:3 189:7,22 190:11,12,13 191:2 191:6 192:5,10 194:7 207:9 210:23 216:8,17 233:3 234:7 235:14 236:3 236:16 237:25 240:5 287:1 298:10 299:5 300:22 305:4 305:5 McGovern's (3) 298:16,19,23 McGrath (2) 4:12 5:14 MD (3) 289:16 293:12 294:3 MDL (2) 1:6 5:9 mean (48) 9:7 12:24 13:4 21:3 29:20 31:9 39:5 43:22 87:19 100:24 103:4 106:1,1 142:2 152:11 161:24 166:21 167:9 171:1 190:11 191:8,14,14 191:20 204:10 213:5 223:22 234:18,20 240:6 247:16,19 248:8,11 248:17,24,25 249:17 272:8 284:1 285:1,14 295:2,5 300:14 305:21 307:8 308:9 meaning (1) 240:5 means (15) 40:19 146:4 166:22 171:2 265:12,13 267:16 268:16,17 269:8 271:9,25 272:3 273:2 289:12 meant (2) 62:24 262:25 measles (1) 183:5 measure (7) 23:15 82:24,25 83:15 83:21 257:22 299:9 measured (8) 22:17 23:5,14 88:23
--	--	---	--	--

92:14 108:12 251:19 253:5 measurement (2) 91:5 215:4 measurements (3) 84:7 100:10 286:3 measures (1) 156:2 measuring (6) 23:19,21 75:21 83:11 108:24 299:15 media (6) 122:2,2,9,25 257:25 276:18 medical (33) 8:5,7 21:8 25:2 29:15 30:13 54:9,15 68:7 128:9 136:6,8,9,10 136:13 146:5 154:6 156:18,25 157:14 161:25 162:24 182:18 187:25 213:20 216:23 245:5 246:22 273:16,18 275:22 306:15 307:8 medical/legal (1) 215:6 Medicare/Medicaid... 156:1 medications (1) 182:19 Medicine (1) 148:21 Medline (5) 104:2,20 105:16 140:9 157:23 meet (3) 68:8 137:19 309:5 meeting (21) 9:1,2,10 12:18 13:20 14:10,21 15:1,5,10 16:6,16,18 17:10 137:11,25 260:22 261:12 263:9 300:6 300:18 meetings (9) 14:14,16,18,19 16:9 16:15 17:8 18:18 19:15 meets (1) 137:20 Memarzadeh (1) 33:23 Memarzadeh's (1) 279:9	Memarzadeh (10) 279:15,19 280:13 281:1,11,16,20 282:8 283:4,12 Memarzadeh's (3) 279:10 281:23 282:23 members (3) 137:12 268:10 302:21 membranes (3) 154:21 170:22 180:10 memo (1) 47:17 Memorex (1) 229:20 memory (2) 35:4 118:13 mention (8) 58:10 75:5,13 164:23 170:10 184:2 282:23 300:21 mentioned (15) 57:8 71:14 156:23 163:4 164:22 172:3 195:21 200:5,6 252:16 259:25 288:12,15 291:12 296:17 mentioning (1) 281:25 merely (1) 268:7 merit (1) 282:23 merits (1) 126:2 MERV (15) 304:9,13 307:1,4,5,13 307:18,23,24 308:5 308:16,17,21 309:5 309:8 messages (1) 203:15 messaging (1) 47:19 met (4) 6:10 150:7 281:20 308:20 metanalyses (9) 58:6 59:21 63:1 64:9 64:16 65:24 67:1,22 68:1 metanalysis (3) 59:9 65:22 157:16 meter (4) 50:4 80:3,7,8 meters (5)	247:14,17,19 248:8,9 methicillin (2) 192:13,13 methicillin-resistan... 7:25 313:21 method (2) 83:2 260:16 methodological (12) 28:4,9 30:1 31:2 43:18 44:22 45:5 51:23 52:3 54:22 65:2,3 methodologies (5) 53:14 90:2 136:7 137:16 147:9 methodology (17) 50:13 51:25 52:23 68:13 69:19 70:4,11 73:3,6 75:3 92:21 142:16 164:11 187:22 283:3,5 301:6 methods (11) 127:11,14 129:5 203:16,17 260:5,8 260:11 282:11 283:21 304:20 mi- (1) 290:20 Michael (2) 262:7 264:19 microbes (2) 255:18 303:23 microbial (5) 46:21,24 49:1 72:4 313:7 microbiologic (1) 290:22 microbiology (3) 148:22 287:22,24 microdata (1) 245:18 micron (6) 78:4 80:5 251:14 290:24 291:14,15 microns (34) 48:25,25 77:22,23,24 78:7,7,11,19 79:10 80:4,5,5,6 86:20 87:5,25 88:9,10,23 88:24 89:15 90:23 90:24 91:2 92:14,15 287:14,17 288:10 288:11 290:21 291:2,8 microorganisms (1)	103:5 middle (4) 215:9 217:3 268:19 296:16 migrate (1) 179:5 migrating (1) 175:21 mind (10) 45:16 79:20 112:6 125:17 155:10 168:4 212:20 237:22 238:1,5 mine (2) 70:17 112:2 minimal (1) 283:11 minimize (1) 183:23 minimizing (1) 180:7 minimum (1) 275:5 ministries (1) 275:23 Minneapolis (2) 4:7 13:20 Minnesota (5) 1:2 4:7 5:9 284:10 285:4 minor (1) 112:24 minute (1) 100:13 minutes (6) 102:16 257:9,14,15 262:7 286:10 mischaracterizatio... 186:2 mischaracterize (3) 30:21 126:8 308:9 mischaracterizes (8) 30:18 72:13,25 116:22 142:8 155:12 238:3 308:7 mischaracterizing (5) 115:1,10 116:5,24 270:23 misheard (2) 94:9 308:10 misquoting (1) 165:11 missed (5) 108:3 115:7 117:16 117:17 133:16 missing (1)	38:9 misstated (1) 64:11 misstates (10) 60:2 68:11 83:23 92:12 93:14 94:2 103:13 104:19 162:14 237:20 misstating (1) 280:17 mist (1) 269:15 MITCHELL (1) 3:3 Mm-hmm (3) 34:3 133:4,10 MMSA (1) 171:14 mock (1) 285:10 modalities (1) 123:25 modality (1) 190:18 mode (2) 184:5,6 model (3) 22:22 23:3 285:14 modeling (1) 281:16 modes (4) 184:24 185:4,13 187:17 modified (1) 57:15 moisture (1) 269:15 molecular (2) 83:6 185:21 moment (3) 195:2 259:2 267:18 moments (2) 53:23 270:20 Monday (1) 219:2 money (1) 148:12 monitoring (1) 183:20 month (4) 140:19 141:5 235:7 284:8 months (4) 61:15 201:21 234:24 236:25 Montrose (1)
--	---	--	--	---

3:20 mop (1) 219:12 morbidly (1) 58:21 Mordecai (2) 4:11 132:2 morning (11) 5:4 6:8,9 26:7 125:15 132:17 160:13 196:21 250:15 299:1 302:15 motion (6) 134:3 228:18,19,20 228:21,22 motor (2) 106:21 221:16 mouth (1) 53:25 move (10) 109:22 110:22 113:7 115:5 117:10 149:18 177:25 246:24 250:4 251:17 moved (2) 82:11 176:9 moves (1) 83:3 moving (1) 226:17 MRSA (25) 118:1,24 119:3,17,18 120:3,15,16,18,25 121:3,10,16,20 122:22 123:6,7 161:5,11 171:14 183:17 184:5,13 188:22,23 MSSA (4) 195:10,17 196:2,3 mucous (3) 154:20 170:21 180:10 muddying (1) 10:5 multi-district (1) 6:13 multi-variable (1) 227:21 multi-variant (1) 114:4 multiple (6) 80:14 84:1 93:7 96:19 97:17 124:6 multiple-point (1) 92:18	multivariate (1) 232:16 mupirocin (4) 171:15,18 195:21,23 muster (2) 65:14,17 mycobacterium (8) 159:15 244:20 245:9 245:19 246:1,19 292:13 315:4 myriad (1) 185:24 <hr/> N <hr/> N (2) 3:1 161:9 name (13) 5:13 11:15 15:24 35:3 81:14 84:25 118:19 130:4 132:4 136:2 197:21 201:15 316:2 names (4) 7:23 16:10 149:16,22 narrow (4) 21:15 52:19 53:12,17 naso-colonization (1) 152:13 national (5) 135:16 201:9 279:20 280:14 287:4 nationwide (1) 287:5 nature (3) 21:18 283:10 305:15 NCRA (1) 2:11 near (5) 46:22 72:4 123:2 249:2,10 Nearing (1) 297:20 necessarily (6) 42:25 156:15 162:16 264:12 268:8 295:5 need (19) 47:23 48:2 58:21 63:21 75:16 88:16 110:7 111:7 113:1 142:5 180:24 181:2 181:4,9 207:25 223:11 243:3 272:5 302:6 needed (5) 109:10 144:25 192:23 234:5 243:12	needing (1) 271:4 needleless (8) 124:7,8,8,13,21 128:11 129:21 314:5 needs (3) 76:23 137:22 180:23 negative (5) 194:19,21 202:23 222:20 300:7 neither (3) 48:22 74:6 305:5 network (1) 287:4 never (8) 69:23 102:7 131:13 150:7 210:9 232:8 278:10 308:14 new (8) 137:4 148:15,20 149:4,7,8,21 200:11 NHSN (2) 286:21 287:3 nice (2) 70:3 308:19 night (1) 219:9 NIH (1) 280:1 Nimbic (2) 81:13,20 nine (3) 255:9,11 257:7 Nineteen (1) 226:6 Ninety (1) 226:7 NIOSH (1) 277:11 Nitpicking (1) 40:20 nits (1) 31:9 no-patient (1) 266:20 Noble (1) 33:23 non- (1) 14:15 non-bacteria-carryi... 89:3 91:19 93:1 non-implant (3) 110:5,15 111:23 non-lawyers (4) 14:15,19 16:8 17:3	non-peer-reviewed ... 282:21 non-randomized (3) 62:4 63:7,19 non-regulatory (1) 277:10 non-risk (1) 266:20 non-turbulent (1) 93:19 nonresponsive (7) 109:23 110:22 113:8 149:18 178:1 246:24 251:17 nonselective (1) 122:9 Nope (1) 150:9 normal (2) 265:17 299:23 normally (1) 161:17 normothermia (8) 35:24 36:1 53:12,14 66:4,14 71:1 303:24 Northumbria (5) 195:6 200:2 201:5,10 299:8 nose (2) 121:23,24 nosocomial (3) 218:8 243:7 245:15 notable (1) 299:19 Notary (1) 316:25 note (5) 7:12 94:16 164:12 184:23 206:23 noted (1) 46:8 notes (9) 75:20 196:21 197:4 197:14 198:11 199:5 297:21 314:19,21 notice (2) 207:9 314:7 noticed (1) 68:21 notion (2) 96:22 288:8 November (2) 205:15 206:4 nozzle (3) 255:10 256:23,24	Nth (2) 231:24 232:9 number (56) 5:5,9 49:5,16 52:7 55:1 61:15 70:5 73:22,23 74:4,4,19 74:20 75:13 79:17 79:18,25,25 95:3 99:4,5,14 100:9 109:10,16 110:6 113:20 117:18 136:12 155:22 157:7 163:5 168:22 174:24 176:11 192:15,17 194:13 202:23 207:6 211:4 219:16 220:9 232:14 248:23 250:13 251:12 274:7,7 277:12 285:14 288:12 297:10 309:4,5 numbers (2) 232:15,18 numerous (3) 264:7 297:15 303:15 nurse (3) 231:21,22,22 nursing (1) 121:12 <hr/> O <hr/> obese (3) 58:19,21,21 obesity (1) 216:20 object (96) 11:1,1 13:23 20:6,12 21:22 23:22 24:23 27:12 29:8 44:17 48:9 49:14 50:16 54:24 59:24 66:12 72:12 75:8 78:15 81:22 82:14 83:23 88:14 89:22 90:12 93:13 111:8,21 112:20 115:3,4,7,22 116:6,10,12,16,21 116:23 125:19,19 126:12 133:17 135:4 141:19 142:7 142:21 146:9,16 147:17 151:4,8 152:10 157:19 159:3 160:21 161:22 172:16
---	--	---	---	---

174:19 175:24 176:18,21 178:8,11 186:10 189:11 194:1,9,22 202:13 203:12 204:8 208:24 212:9 213:6 223:8 224:18 225:16 228:11 229:21 232:21 240:23 241:13 253:12 259:6 268:18 269:9 270:22 271:10 272:1 279:22 280:16,16 282:1 303:6 objected (1) 223:12 objection (88) 30:14 39:18 40:5,20 42:9 48:20 68:10 72:16,24 84:12 87:11 90:19 91:23 92:11 94:1,16 95:22 96:24 98:10,25 99:19,22 100:4,22 103:12,25 104:18 106:24 109:3 110:24 111:18 113:14,22 114:25 115:6 116:17 118:2 123:11 128:7 129:10 130:22 138:24 149:24 150:14 155:11 162:13 163:2 165:10 168:9 179:6 180:1 186:1 187:6 189:23 212:22 215:25 218:19 230:15 235:22 237:19 238:2,23 242:21 243:20 249:21 251:21 252:7,21 253:22 259:20 260:9 263:15 267:14 272:14 273:4,13 274:1 282:25 291:19 293:4 294:7 295:8,24 296:9 298:25 305:24 306:6 308:6 objections (1) 115:21 objective (1)	126:1 OBs (1) 62:5 observational (5) 62:4 63:8,19 189:10 200:4 obtain (1) 279:14 obviously (32) 9:9 16:16 20:9 22:13 24:25 27:5 52:4 53:3,18 80:13 84:1 84:4,7 86:7 99:10 107:1 115:13 126:15 129:18 146:19 175:1 186:13 188:4 202:22 204:17 212:12 246:10 249:24 250:20 274:9,19 290:18 occasion (1) 61:8 occasionally (2) 136:6 275:24 occasions (2) 117:18 288:13 occur (6) 151:22 158:15 161:8 188:18 203:19 224:14 occurred (7) 99:6 167:24 192:16 192:18 195:5 236:17 298:20 occurrence (1) 188:13 occurring (10) 159:16 171:9 187:4 191:12 202:22 234:16,21 235:1,4 241:4 occurs (1) 162:5 October (3) 199:20 200:23,25 odd (1) 49:16 odds (3) 208:9,10,22 offer (1) 6:14 offering (1) 8:2 offhand (8) 25:17 26:4 38:7 40:15	41:16 73:19 95:18 288:22 office (5) 284:11,13,25 285:3,4 official (3) 263:12 264:5,15 Oguz (4) 107:18 117:12,13 313:25 oh (17) 19:20 35:9 64:10 78:22 125:6 155:3 185:6 200:12,19 201:4 213:7 223:2 224:6 225:3 235:11 243:22 261:24 okay (135) 6:23 7:14 8:21 11:13 18:17 19:20 22:7,10 24:11,20 27:5 28:19 31:13,21 32:1,5,6 32:11,12 33:2,11,18 34:16,18 35:11 36:19 38:2,8,14 39:22 41:3 54:3 57:14 61:23 63:3 64:10 65:22 67:14 68:6 73:5 76:11 79:10 83:18 85:3 90:24 91:17 93:9 97:11,21 98:1,8 100:1 101:5 102:10 103:17,21 105:21 107:12 117:17 119:12 124:12 126:17,24 133:13 134:24 136:23 140:18 141:8,25 144:6 145:7 153:9 154:3 156:17 158:23 164:6 165:1 165:20 166:4,20 167:22 169:21 182:7,15,21 183:2,8 191:5,9 198:20 199:3 205:19 207:18 211:3 212:6 212:24 213:13 220:2 222:16 227:4 235:14 237:22 239:16,20 241:10 243:4 248:4,5 257:12 258:23 259:1 262:2 263:11 264:3,14 265:7 266:9,24 267:3	276:8 280:4 281:19 282:7 284:6 285:17 285:25 287:23 288:15 290:4,7,9 299:5 300:8,16 302:19 old (1) 56:9 on-site (2) 29:14 276:20 once (3) 127:7 175:22 257:4 one-hour (1) 276:6 one-on-one (1) 124:17 ones (10) 33:11 34:14 41:10,11 41:13 90:8,16 183:9 292:15,17 ongoing (2) 188:4 276:9 online (7) 61:1,5,9,12 148:25 260:25 313:15 open (4) 45:16 237:22 238:1,5 Openly (1) 244:22 operating (52) 42:19 48:6,16 49:23 49:24 50:5,7 87:8 106:3,8 107:1 109:17 155:16 177:20 185:9 218:11 219:2,9 220:10 223:23 224:4,8 225:12 226:13 227:12,13 230:21 231:23 238:10 248:1 249:8 249:10 250:4 256:14 262:15 264:17 265:21 266:3,6 273:16,19 274:9,21 283:23 284:20,23 300:24 307:15,18 308:3 313:8,18 operation (11) 87:8 88:3 109:16 155:18 167:12 168:1 218:15 221:4 251:6 283:15 300:24 operative (13)	46:22 80:24 99:9 147:1 166:7,14 169:4 170:3 177:22 179:18 299:21,25 315:13 operative/incision (1) 72:5 opinion (33) 24:22 25:12 28:7 32:4 32:11 35:12 44:23 46:5,7 47:25 51:24 52:25 61:8 66:20 69:1 70:6,12 103:11 103:23 107:25 108:5 138:13 141:17 147:12 189:7 248:25 249:20 250:17 290:14 298:24 302:16 306:19,19 opinions (14) 8:2 24:4,8 45:1 138:12 141:9 146:2 146:6 218:20 286:11 289:16 301:3 306:2,14 opposed (7) 19:15 111:3 137:22 140:14 256:24 257:23 276:9 opposite (7) 111:13 112:14 153:6 207:17,19,22 296:1 order (2) 248:16 277:11 Oregon (1) 14:10 organism (7) 110:10 159:9,11 166:23,23 167:6 289:2 organism-specific (1) 120:2 organisms (22) 35:25 42:18 109:10 110:6,8,11 151:15 155:15 162:19 167:5 173:19,20 174:4 176:25 177:1 177:17 180:14 185:21 202:24 203:3,4 246:18 organization (2) 13:4 277:3 organizations (1) 275:23
--	--	---	---	---

<p>originally (2) 127:3 144:18</p> <p>orthopedic (18) 48:6,16 69:22 101:11 107:17 108:14,16 148:4 172:1 174:14 196:7 198:1 201:11 210:9 278:16 283:20 300:18 313:24</p> <p>orthopedists (1) 210:6</p> <p>outbreak (47) 28:21,23 29:7,20 30:2 30:3 152:25 159:2 160:19,22 185:10 188:4,5,8,11,17 188:25 189:3 190:2 201:8 202:11,16,21 203:15 204:11 205:4 207:5 219:6 233:10,15,21 234:2 234:8,12,19 238:6,7 240:14 242:12 244:19 276:20,22 277:16,19,21 303:10</p> <p>outbreaks (22) 28:14 105:4,5 153:1,3 154:11 157:6 158:2 158:3,20 163:22 182:17,18,21 183:5 183:11 185:12 187:20 218:23 219:16,25 234:21</p> <p>outcome (5) 85:24 112:21 243:11 278:3 311:18</p> <p>outlet (1) 247:15</p> <p>outlier (1) 201:11</p> <p>outside (7) 22:1 55:15 152:20 283:23 284:20 299:25 308:18</p> <p>outtake (1) 94:23</p> <p>overburdensome (1) 55:13</p> <p>overcome (1) 249:18</p> <p>overkill (1) 243:9</p> <p>overlap (3) 89:16 143:25 144:2</p>	<p>oversight (1) 264:1</p> <p>overwhelming (1) 158:14</p> <p>owner (1) 13:10</p> <p>owners (1) 13:15</p> <p>oxide (1) 106:18</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p>P (5) 3:1,1 78:6,19 232:6</p> <p>P-A-R-V-I-Z-I (1) 34:14</p> <p>p.m (18) 132:6,8,8,11 181:11 181:13,13,16 243:24 244:1,1,4 297:22,24,24 298:2 309:23 310:5</p> <p>page (76) 7:6,18 26:15 28:2,12 28:20 29:21 46:13 57:19 61:24 71:22 71:23,25 72:1 73:9 73:15 77:8 86:15 91:3,25 118:12 148:16,16,21,21,23 149:1 150:20,20 154:14,16 163:17 166:9,10 170:19 182:22,23 183:17 184:4 187:16 199:12,18,19 206:23 208:7 213:16 216:18 230:24 231:8,8 246:25 247:11 258:24 261:18 262:4 265:2,7 266:12 267:4 269:11 270:6 271:16 278:23 283:4,5,5 286:16,18 286:20 296:15,23 296:24 312:4 313:1 314:2 315:2</p> <p>pages (1) 314:18</p> <p>paginated (2) 112:1,2</p> <p>paid (3) 13:7 143:2 280:10</p> <p>paint (4)</p>	<p>223:23 224:3,9 225:6</p> <p>painter (2) 224:9,14</p> <p>panel (2) 136:3,4</p> <p>panels (1) 135:13</p> <p>PAPANTONIO (1) 3:3</p> <p>paper (72) 34:5 35:4 69:17 70:17 71:16,16,20,21 72:9 72:11,19,23 74:21 77:9,20 82:12 84:1 84:2,3,18,18,21,21 86:8 96:20 107:16 111:25 117:12,13 118:18 126:2,23 130:3 133:2,6,15,23 134:7 135:1 145:6 148:11,13 149:14 157:13,24 169:8 170:7,13 171:7 182:3,9 191:3,6 204:25 207:9 209:7 211:6 212:1 216:17 226:12 233:3 234:20 235:14 236:3,16 237:25 244:14 247:11 250:20 264:10,11 282:10</p> <p>papers (19) 36:3,4 42:17 46:18 59:17 75:13 95:17 95:20 98:19 99:4 148:5,8 157:7 163:5 189:6 190:1 203:20 305:10,12</p> <p>paragraph (22) 61:25 86:16 88:8,22 91:3 152:16 154:15 164:23,24,25 166:13 170:20 183:24 217:2,3 231:8 247:13 267:17 270:7 286:19 296:16,16</p> <p>paragraphs (1) 183:25</p> <p>parameters (3) 35:16 39:3 276:17</p> <p>parse (1) 234:17</p> <p>part (35) 15:14 20:20 51:13,16</p>	<p>52:14 84:6 106:11 106:21 116:19,20 119:21 145:9 149:19 152:23 171:10 172:3 173:10 185:14 198:17 199:13,15 202:5 216:13 222:17,20 270:9 281:13 283:19 290:5 291:10 296:21 297:3 300:5 300:22 303:3</p> <p>participants (1) 15:2</p> <p>participated (1) 16:9</p> <p>particle (44) 46:21,24 48:7,18 49:8 50:9 72:3,6 73:16 73:17,19 77:21,25 78:2 80:3,12 86:6 88:22 89:13,25 90:5 92:9,13 95:20,25 96:2,4 97:8,15 101:9 105:11,12 110:5 147:1 288:20 289:5,7 291:2 295:11,22 296:2 299:20,24 313:17</p> <p>particles (79) 22:17 23:5,21 50:3,6 73:23 74:4,9,19 75:22 76:1 77:9,11 77:17 78:12 79:14 79:18,25 80:3 81:7 81:10,16,16 82:6,10 86:19,21,22 87:4,25 88:9 89:4,12,20,21 90:9,11,13,17,22 91:5,13,19,21 93:1 93:11 96:23 97:24 99:8 100:2 103:9,11 103:18,19,21 105:13 108:22,23 197:10 251:1,1 289:6,11 290:14 291:9,13,15 294:11 294:23,24 295:3,6 295:14 299:9,16 300:23 303:18,22 303:25</p> <p>particular (13) 13:3 79:12 127:12 142:11 158:4 167:11 168:3</p>	<p>180:16 208:17 213:19 235:20 258:20 299:18</p> <p>particularly (13) 42:14 80:22 147:3 148:24 167:24,24 168:6 188:19 218:25 219:1 270:4 305:4,17</p> <p>particulate (7) 83:13 93:17 95:4,14 291:5 304:8 313:7</p> <p>particulates (24) 46:15 48:23 80:7,15 80:23 81:2 82:20,21 82:22,24,25 83:12 83:16,21 84:6,10 94:5 99:6 197:18 198:5 290:17,18 297:16 304:23</p> <p>parties (2) 29:15 311:16</p> <p>parts (7) 28:14,15 84:19 96:19 234:5 260:25 261:16</p> <p>Parvizi (2) 34:12,14</p> <p>pass (1) 65:17</p> <p>passed (1) 65:14</p> <p>passive (4) 221:16 228:18,21,22</p> <p>pathogen (7) 150:23 151:6,10 160:24 161:18 183:23 193:19</p> <p>pathogens (11) 154:19 155:5 164:1 165:22 169:6 183:3 183:15 191:15,16 250:12,17</p> <p>pathogens' (1) 170:5</p> <p>patient (55) 69:21 91:9 96:14 98:6 98:9,21 99:7,10 100:3,8,9 102:21,24 103:2 106:12,14,16 109:12 110:14 111:10 121:1 152:8 152:21 153:5,15 167:19 168:17 174:14 177:11 178:3,4,5,6,7,17</p>
--	---	---	---	---

179:16 186:16 221:20 230:11 233:12,23 235:15 236:8 239:3 240:10 240:21 249:12,14 250:3 251:12 266:19 285:10,10 289:20 295:19 patient's (7) 154:20 164:1 171:2 171:13 180:15 188:20 214:21 patient-specific (4) 150:22 151:19 152:7 153:10 patients (72) 58:19,24 67:25 95:12 95:15 96:18 97:16 99:18 100:18 104:11 107:10 111:14 112:16 114:5,15,17,19 119:3,17 120:15,17 120:19,25 121:5,6,7 121:13 147:3 155:23 158:23 159:17 165:23 167:13,24 168:13 172:2 178:22 183:24 185:8,8 206:25 213:21,22 213:23,24 214:15 214:22 215:2,7,14 217:7 225:9,10,13 225:21,22,22 226:2 226:20 230:7,8,11 230:22 231:4 232:14 238:9 239:11 245:7,19 249:24 305:17,20 pattern (4) 161:13 187:24 191:6 191:8 pay (1) 148:10 PCR (3) 122:5,6,8 peaks (2) 91:6,11 pediatrician (1) 278:5 peer (6) 44:20 128:22 147:25 149:5,22 282:6 peer-re- (1) 149:22	Peer-review (1) 125:13 peer-reviewed (19) 27:20 31:12,17,20 58:4 70:17 125:7,9 125:17,25 147:6,20 147:24 245:8 280:2 281:5 282:4,16 308:22 peer-reviewers (2) 126:5,9 pending (1) 169:23 Pendley (2) 3:11 5:23 Pensacola (2) 3:7 15:6 people (21) 15:23 17:6 51:16 52:13 86:4 109:16 109:19 129:19,20 135:20 144:24 149:17 177:5,6,15 201:23 203:21 219:11 272:17 273:10 277:16 percent (13) 79:2,5 114:20 165:5,8 206:6 208:4,4 230:12 275:14,15 304:16 309:11 percentage (2) 40:17 275:11 perfectly (3) 50:17 110:24 159:14 performance (1) 278:17 peri-prosthetic (6) 66:8,18 67:14 183:16 287:11 292:16 period (30) 61:18 101:14 180:8 188:22 189:3 191:13 192:17,19 193:6,10,22 194:15 194:17 195:6,7 202:10 205:9,25 206:1,2,5 222:12 227:19 234:22,24 234:25 235:3,6 238:13 240:20 periods (3) 127:13 240:18 305:8 peripheral (1) 214:17 periprosthetic (2)	305:21 314:13 permutations (1) 303:24 person (6) 12:6 15:22 176:15,16 176:16,17 person's (2) 15:24 176:12 personal (5) 70:6,12 136:3 163:19 163:21 personally (3) 52:11,23 85:8 personnel (10) 121:12 155:16 185:19 186:15 219:10 220:9 226:13 237:3 237:4 309:3 personnel-intensive... 55:12 pertinent (2) 241:18,22 Petty (1) 33:23 Pg (1) 316:5 pharmacologic (1) 58:20 phone (3) 12:2 17:11,13 phonetic (4) 85:10 96:5 102:14 197:22 phrase (5) 43:19 88:14 125:16 167:9 190:23 physical (3) 214:10 216:9 239:21 physician (2) 11:16 16:3 pick (5) 31:9 44:10 149:13 157:23 158:20 picking (2) 44:25 149:12 picture (2) 295:17,19 pictures (1) 295:12 piece (8) 126:23 141:13,22 146:5,22 147:5 262:19 282:9 pieces (2) 141:12 295:14 pile (1)	14:20 pilot (2) 107:18 313:24 PJI (2) 67:15 176:17 PJIs (2) 67:20 69:7 place (2) 121:7 177:10 placed (2) 168:1 308:15 places (5) 36:14 226:25 227:2 242:19 250:8 Plaintiff (1) 3:2 plaintiff's (2) 20:19 280:24 plaintiffs (8) 5:22,24 6:1,13 8:3 66:16 67:13 282:22 plaintiffs' (3) 10:13 280:7,10 planet (1) 153:2 plant (1) 246:5 Plaquemine (1) 3:14 plastic (2) 179:15,20 plate (4) 100:12 256:10,17,25 plates (10) 100:21 114:8,9 254:11 255:11,14 255:15 256:23 257:5,18 play (1) 228:10 Plaza (2) 2:5 5:12 please (12) 5:17 6:3 36:10 37:23 48:12 51:9 87:18 94:8,17 267:24 269:10 289:14 Plus (2) 290:22 297:15 point (37) 9:5,8 10:16 14:13 33:4 42:13,23 43:16 44:3,11,15 45:20 48:22 50:24 54:6 69:11 92:3 93:7,7 93:22 94:12 100:7,9	112:23 113:3 119:13 120:20 148:11 162:24 165:21 180:24 196:10 201:19 223:13 251:3 253:10 290:10 pointed (4) 49:5,10 285:20,20 points (3) 27:21 43:1,11 polymerase (5) 83:5 122:1,4,8,24 Pontiac (1) 183:7 populations (2) 153:15 236:8 portion (2) 38:3 108:23 Portland (2) 14:10 15:1 position (4) 133:25 187:13 264:5 264:15 positive (3) 195:17 255:12,13 possibilities (3) 162:3 186:4 303:14 possibility (10) 49:7,20 167:15,21 177:21 198:4 204:19 227:5,8 231:1 possible (3) 179:9 204:7 232:12 possibly (3) 36:6 71:10 160:6 post (1) 164:19 post- (1) 221:16 post-discharge (1) 202:1 post-operative (2) 220:19 221:24 poster (1) 289:16 potential (19) 55:7 58:8 128:15 183:5 185:20,25 197:16 202:11 222:25 223:10 224:16,22 225:24 227:25 229:5 243:12,13 274:11 313:18
--	---	--	---	---

potentially (8) 171:14 186:16 223:18 226:9 232:2,10,11 235:11	preferred (1) 172:23	183:19 186:23 198:3 313:10,12,13	242:11 243:1,2,3,6 263:19 275:14 279:1 283:18 287:21 288:19 289:21 290:3 292:24 293:2 296:10	21:24 123:17 135:6 266:14 304:3
potty (1) 76:23	premises (1) 103:10	preventive (1) 183:21	problem (11) 43:3 202:12 209:25 224:7 228:24,25 230:3,9 232:7 270:14 274:18	products (3) 1:4 5:8 122:15
povidone (18) 156:8,11 172:8 173:15,17,19,21 174:1,7,10,15,24,25 175:3,4,10,16 179:14	preoperative (9) 214:10,13,23 216:9 217:21 221:10 239:14,19,21	previous (1) 274:8	problematic (1) 237:15	Professional (2) 2:8 311:6
Power (1) 59:14	prep (14) 38:9,12,14 171:6 172:23 175:2,2 176:4,11 177:13 179:4 186:25 196:9 196:14	previously (9) 91:4 120:21 192:5 209:5 224:21 258:5 296:17 298:10 301:13	problems (2) 70:1 131:1	Professionals (1) 60:16
practical (1) 121:12	preparation (9) 22:21 36:18,22,25 37:8,12,15,18 153:23	primarily (8) 27:20 31:6,8,19,19 80:17 136:5 253:15	procedure (15) 102:16 109:19 110:2 110:3,6 173:25 177:5,15 187:2 196:6 219:14 220:10 222:12,13 299:8	program (2) 52:9 119:16
practice (1) 148:24	prepare (1) 172:7	primary (4) 50:1 172:11 173:14 231:16	procedures (15) 49:2,3 53:8 68:14 71:4 108:16 110:16 111:23 169:2 171:5 201:21,24 219:23 227:13 236:24	prohibited (1) 139:11
practices (5) 52:5 137:7 200:2,10 315:8	prepared (3) 26:12 51:17 144:24	printed (1) 191:22	procedure-specific ... 286:22	project (6) 198:6,14,16 199:16 276:10 304:19
practicing (1) 275:25	preparing (3) 19:3 25:15 26:3	printout (1) 132:18	proceed (1) 6:3	prominent (1) 292:16
pre-date (1) 199:9	prepped (2) 174:15,17	prior (19) 9:14 27:6,8 32:19,23 33:8 34:19 35:7,12 41:12 43:9 47:25 195:6 199:21,24 200:3 214:7 257:14 259:1	proceeding (1) 310:5	Promotion (1) 262:9
pre-dated (1) 265:22	presence (4) 109:20 218:1 220:12 242:25	private (1) 278:2	proceedings (2) 97:20 260:21	pronounce (1) 197:21
pre-epidemic (1) 206:1	present (7) 4:11 17:3 23:11 69:20 83:22 91:13 255:18	privilege (5) 20:9,13 21:24 133:21 135:7	process (13) 55:15,19 125:10,24 235:24 264:4,6,9 265:17,19 280:2 302:22 303:4	pronounced (2) 84:25 85:15
pre-filter (1) 307:23	presentation (3) 262:7 276:6,9	privileged (2) 11:2 20:25	processes (1) 264:7	pronouncement (2) 263:12,13
pre-meeting (10) 36:18,22,25 37:8,12 37:15,18 38:9,11,14	presentations (1) 137:12	probability (1) 306:16	processing (1) 267:6	pronouncing (1) 85:7
preamble (1) 176:22	presented (4) 126:6,10 127:11 128:22	probable (1) 243:10	PROCTOR (1) 3:4	properly (2) 50:14 183:22
precise (2) 94:10 250:24	presumably (1) 80:23	probably (59) 15:18 19:10 25:21 26:23 32:1 35:10,18 40:12 58:2 61:19 100:13 101:13 102:15,19 117:22 123:6 138:1 140:24 140:25 141:2 144:9 154:1 158:6 159:1,8 159:19 160:2,24 161:13 164:4 174:12 177:7 185:20 188:5 196:19 201:17 202:2,4 215:6 219:24 223:11 224:10 225:11	produce (2) 99:8 151:24	prophylactic (9) 58:22 156:6 168:25 169:9 170:8,15 171:7 186:25 314:14
preconceived (1) 45:8	prevent (1) 120:14		produced (2) 92:5 194:6	prophylaxis (3) 58:18 220:22,25
Predict (1) 313:7	preventing (4) 66:5 67:23 171:12 184:1		producing (2) 103:5,7	proportion (2) 103:19 105:13
predicted (1) 229:8	prevention (13) 51:11,11 53:5 62:12 156:3 171:11 172:3		product (9) 8:5 11:2 20:9,13	proposed (2) 20:11 58:2
predictors (1) 216:22				proposition (2) 74:18 154:7
predominantly (2) 162:12 210:8				pros- (1) 220:3
prefer (2) 210:11,11				prosthesis (2) 167:25 220:3
preferable (1) 173:25				prosthetic (33) 35:20,23 65:20 66:2,5 67:24,25 68:3,4,19 71:2 104:11 105:20 108:19 110:20,21 147:4,9 152:1 165:25 166:3,24 168:14 177:4 178:23 184:3 198:3 202:24 236:7,11
preferably (2) 149:16 171:6				
preferentially (1) 195:8				

<p>287:7 305:18,20 protected (3) 20:12 21:24 135:6 Protection (3) 201:15 236:6,23 proteinaceous (3) 173:22,24 174:8 protocol (12) 19:25 20:3 22:25 24:7 24:16,21 25:1,7 37:25 38:3,19 195:10 prove (1) 232:1 proved (1) 162:9 proven (1) 171:22 provide (7) 87:5 88:1 93:7 137:11 149:16 280:25 293:15 provided (9) 8:15 41:5,14,18 93:4 140:3 142:23 283:3 293:14 providing (2) 269:23 283:20 Pseudomonas (1) 204:14 public (4) 61:17,17 117:24 316:25 publication (10) 42:15 105:19 147:22 148:14 200:23 264:8 281:5 282:4 282:13,18 publications (1) 59:16 publish (3) 84:17 148:10 264:10 published (17) 58:3 60:25 61:14 63:1 70:2 120:21 121:9 125:7 149:7 157:13 157:14,15 162:24 163:7 200:25 245:15 304:4 publishing (1) 148:8 PubMed (12) 35:15,17 37:3 38:6 39:4 40:4,11,18 44:8 70:24 71:7 303:15</p>	<p>pull (2) 115:24 169:7 pulled (4) 51:17 75:20 127:24 213:20 pulls (1) 206:17 pumps (1) 137:15 purported (1) 190:16 purpose (3) 69:20 80:10 216:2 purposes (2) 80:13,14 pursuant (1) 24:20 put (19) 43:3,6 53:24 59:17 60:15 85:8 100:11 164:20 174:7 215:24 257:4,4 261:9 265:13 266:21 279:18 286:5 294:9 309:4 putative (1) 189:3 Puts (1) 203:24 putting (5) 96:12 102:19 141:12 258:1 308:18 puzzle (3) 141:12,22 146:22 puzzled (1) 219:20</p> <hr/> <p style="text-align: center;">Q</p> <hr/> <p>qualitative (1) 248:25 quality (2) 262:9 313:17 quantitate (1) 256:8 quantitated (1) 255:16 quantitative (3) 178:17 248:20,23 question (70) 18:1 21:12 36:13 43:11 45:19 48:11 52:20 53:21 66:7,23 69:14 72:17 73:21 79:22 82:15 83:20 86:23 94:8 98:16 109:24 111:8 112:3</p>	<p>112:12 113:24 116:7,19 122:19 131:16 133:17 134:20 143:12 149:19 153:9,13,19 157:10 159:23 161:19 162:23 164:16 165:18 168:4 169:23,23 176:11 178:25 189:17,20 196:17 198:22 203:9 206:10,13 240:9,12 240:13 241:19 242:15 243:17 250:24 263:18 266:14 267:22 268:25 288:6 289:14 293:17 302:5,23 303:7 question's (1) 66:15 questioned (1) 303:3 questioning (2) 5:18 32:8 questions (10) 17:16,17,19,21 44:9 82:23 127:10 129:5 150:19 187:12 quick (2) 203:20 302:5 quiet (1) 278:1 quite (3) 53:20 149:6 205:13 quote (4) 42:20 46:17 219:2 247:1 quoted (3) 141:11 262:13 265:20 quoting (6) 42:14 43:2,5 71:17 150:10 198:11</p> <hr/> <p style="text-align: center;">R</p> <hr/> <p>R (7) 1:16 2:4 3:1 310:7 311:11 312:2 313:3 R-A-V-A-L (1) 76:10 RAFFERTY (1) 3:3 raise (2) 139:8 223:1 raised (6)</p>	<p>82:23 127:11 129:1 138:8,17 293:22 ran (1) 286:7 random (1) 149:13 randomized (47) 50:20 51:3 54:1,9,16 56:10,13 58:5,11,24 59:4,9,20 60:9 62:2 62:25 63:7,8,18,20 64:4,5,8,15 65:18 65:19,25 66:9 67:1 67:5,6,18,21 68:1,4 68:17 80:17,18,20 80:21 83:14 107:18 113:3,18 175:9 196:1 313:24 range (15) 50:3,9 53:19 77:21 86:19 87:5,25 91:6 276:19,21 286:9 287:14 288:20 290:21 293:2 ranges (2) 89:14 276:17 ranging (1) 307:5 rare (2) 113:2 244:20 rate (38) 188:14,22,24 189:1,2 189:2,4 202:3,6 205:23 206:12,25 209:12 210:18 212:14,15,19,20 223:19 225:2 227:18,18 228:5 229:13 230:13,19 230:21 235:21 236:1,1,11 237:10 237:22 238:7 240:10 242:19 276:4,13 rates (23) 201:12 208:11 209:9 209:10 211:16,22 212:13 213:9 224:17 225:2 229:18 235:16,18 238:10,12 242:3,17 242:17 275:1 286:22 287:1 314:4 314:13 rating (1) 215:15</p>	<p>ratings (1) 226:20 ratio (1) 207:10 Raval (4) 76:5,9,17 83:1 RCTs (2) 62:3,7 re- (1) 175:21 re-operation (1) 222:13 reach (2) 190:7 229:3 reached (4) 247:14,17 248:3 257:16 reaches (1) 188:14 reaction (5) 83:5 122:1,4,8,24 read (79) 23:9 27:4,22 31:22 32:19,23 33:7 48:13 48:14 49:19 63:10 63:12 77:14,15 79:22,23 86:25 87:1 87:9,10,17 88:5,12 88:18 89:7,8 92:2 94:8,11 111:6 112:5 112:13 129:12 133:3,11 142:10 143:6,10,18,24 145:3,6,7,16,19,21 145:23 148:4 154:16 169:25 170:24 190:1 193:2 193:14 195:16 199:21 217:4 233:16,18 245:17 247:21 259:11,11 259:14 261:1,16,17 265:9 267:24,25 270:21 279:10 281:7 298:22 299:5 301:15 302:22 310:2 316:5 readable (1) 266:11 reading (14) 36:5 39:6,9 57:18 68:23 108:11 112:6 112:7 134:15 142:15 201:8 247:22 298:15 299:6</p>
--	---	---	---	---

Reads (1) 316:5	301:20 302:17	redundant (1) 158:21	44:11	reliable (2) 125:18 146:4
real (3) 111:14 112:16 285:10	recalling (1) 98:23	Reed (8) 96:5 143:18 144:3	regarding (3) 181:25 230:25 268:10	reliance (4) 30:10 141:20 189:15
real-life (1) 209:3	receive (2) 270:3 271:24	200:7,15 250:23	regardless (2) 177:3 201:1	189:15
realistically (1) 224:15	received (1) 305:5	300:22 305:5	Regents (5) 127:8 128:13 129:3	relied (4) 65:13 67:6 73:9
realize (3) 13:24 201:4 277:9	Recess (5) 77:1 132:8 181:13	Reed's (3) 193:14 195:16 201:9	129:21 130:10	189:15
really (45) 17:23 36:13 67:12	244:1 297:24	refer (9) 6:24 27:24 28:15	Registered (2) 2:8 311:6	rely (8) 24:5 36:10 67:18
69:18 86:1,6 101:9	recognized (2) 159:14,21	29:25 83:1 145:8	regression (1) 231:12	100:1 141:16 189:6
104:9 108:18	recollection (3) 140:13 145:4 287:25	250:8,20 267:17	regular (1) 183:20	189:22,24
112:25 129:24	recommend (5) 89:4 91:21 92:9 93:2	reference (29) 20:2 27:25 31:21 36:9	regularly (2) 137:19,23	relying (4) 96:22 147:15,18,20
130:13 131:11	172:1	36:11 42:8,15,17,21	regulatory (1) 139:5	remain (1) 179:3
137:18 153:13	recommendation (2) 268:12 270:11	43:17 52:21,25	rehabbing (1) 221:21	remainder (1) 41:4
156:4,12,13 168:16	recommendations (5) 28:17 57:16,23 60:15	71:15 73:13,15	reinterpreted (1) 268:7	remember (58) 7:23 12:8 14:17 15:16
170:12,13 171:11	149:9	91:10 141:16,25	rejected (2) 142:5,10	15:24 16:4,10,13,13
178:24 201:2 202:2	recommended (7) 113:5 121:3 123:16	158:6 164:8 168:22	relate (1) 183:15	16:19 17:5,12,21
203:3,16 210:20	203:18 307:10,13	168:24 198:12	related (8) 12:3 13:19 14:6 24:21	18:17 31:25 34:21
225:15 230:6	307:15	199:20 244:8,15	65:11 219:4 269:15	34:25 48:1,4 49:4
231:25 232:15	record (44) 9:25 10:6 13:22 48:14	281:11 298:17	311:15	49:17,19 61:20
235:5 236:4 241:11	53:24 63:12 76:25	307:1	relates (3) 1:7 122:20 165:18	73:19 81:14 95:18
245:16 246:11	77:5,15 79:23 88:13	referenced (7) 26:25 27:7 49:12	relating (3) 23:20 67:13 138:5	99:21,23 108:7,9,10
247:7 249:5 269:8	89:23 94:11 112:13	71:16 190:13,16	relation (2) 88:25 92:16	108:11,15 131:19
271:8,24 292:23	131:25 132:7,12	306:3	relationship (4) 10:20 12:5 86:19	140:5,12 145:11
297:17 305:14	160:7 165:14	references (21) 27:9,17,19 32:18	163:8	195:18,24 200:6,17
realm (1) 35:10	169:25 181:6,12,17	33:15 36:4 40:16	relative (3) 163:8 190:17 221:1	201:13 210:4 212:4
realtime (7) 2:9,10,12 83:2,6	182:7 187:5,25	42:6 43:3,4,10 44:2	relatively (4) 53:17 203:23 234:22	226:8 237:12
311:7,8	193:25 194:9,23	54:12 107:25	244:20	258:10,13,14
reason (14) 13:3 49:11 83:1 84:7	215:25 216:24	117:14 141:23	release (1) 105:10	259:24 260:2
110:1 173:14	233:18 243:25	168:12,12,17	released (3) 138:17 177:20 246:14	281:17,19 293:20
185:23 202:5 210:5	244:5 260:21	258:11 261:2	releasing (4) 246:1 249:14,15	299:3,6,17 300:9
222:20 243:9 277:1	261:13 267:25	referred (7) 86:13 102:7 162:8	250:2	removal (1) 91:8
277:6 316:5	273:14 297:23	182:10 267:20	relevance (1) 146:1	remove (3) 80:23 81:16 175:20
reasonable (1) 306:15	298:3 302:20	271:15 290:8	relevant (7) 23:20,25 27:11,24	removed (2) 81:11 172:18
reasonably (1) 229:17	309:24,25 311:14	referring (8) 43:5 72:2 75:25	44:24 249:5 301:2	removes (2) 86:5,5
reasons (5) 62:8 72:20 156:23	records (6) 21:9 29:15 128:15	139:20 165:11		removing (2) 81:6 82:9
172:20 215:6	202:2 213:20,21	182:9 251:7 262:19		render (1) 302:16
recall (32) 15:20,22 16:9 18:20	reduce (3) 155:24 169:11 171:23	refers (2) 26:20 57:15		rendered (4) 47:25 108:5 290:13
35:16 49:3 68:23,25	reduced (1) 230:10	reflect (3) 9:25 18:22 19:3		298:23
69:3 76:21 77:9,11	reduces (2) 121:10 174:4	reflected (5) 16:7 23:6 25:16 35:5		rendering (2) 35:12 61:7
77:16 97:21,23	reducing (3) 121:2 171:8 283:21	237:6		Repeat (3) 48:11 72:17 289:14
118:23 140:6 200:9	reduction (2) 81:3 119:18	reflective (1) 27:3		repeated (1)
201:6,8 207:12,20		reflects (7) 9:1 12:18 13:19 14:20		
212:4 236:10 260:4		14:25 15:9 162:16		
261:11,12 278:24		refute (1)		
278:25 298:15				

304:24 repeatedly (2) 253:16 261:8 repetition (37) 33:20 34:13 35:21 58:14 78:18 90:14 96:1 97:2 98:2 109:6 113:13 119:5 120:5 122:3 131:9 132:3 136:17 144:16,20 156:9 161:3,7 171:17 173:2,6,16 179:12 194:20 195:22 197:23 200:24 211:14 216:15 252:12 255:7,20 292:18 replacement (7) 108:18 169:1 207:1 208:10,11,12 239:11 Replacements (1) 314:16 replicated (1) 215:19 report (111) 6:14,21 7:3 8:9 19:4,8 23:6,7,9 25:16 26:3 26:18,24,25 27:4,6 27:8,11,19,22,24 28:2,11,13,15 30:9 30:18 31:22,22,24 40:9 41:12 42:13,21 43:25 45:12 46:2,14 49:13 65:2,13 70:10 71:14,23,25 72:1 74:22,23,24,25 75:4 76:15 116:7 140:20 140:21 141:11,23 142:1 143:24 145:4 150:11,19 154:4 155:6 163:17 165:7 181:20 187:11 190:7,14,16,22 199:9,13,14,18,22 199:24,25 200:10 200:17 201:3 203:20 216:2,3 244:9,9,15,25 245:12 247:1 250:8 250:21 258:18,20 262:14 278:23 279:13 281:7,14,25 282:24 286:17 288:16 290:8	296:15 300:21 302:16 306:4 313:2 315:7 reported (7) 161:5 211:16 216:14 236:3 245:8 246:18 249:3 reporter (66) 2:8,9,9,10,11 5:15 6:2 33:20 34:13 35:21 50:23 58:14 64:5 70:19 74:14 78:18 79:4 80:19 90:14,21 96:1 97:2 98:2 109:6 112:4 113:13 115:11,19 116:4 119:5 120:5 122:3 131:9 132:3 136:17 144:16,20 148:18 156:9 161:3,7 171:17 173:2,6,16 179:12 180:23 181:10 194:20 195:22 197:23 200:24 211:14 216:15 227:1 252:12 255:7,20 273:17 292:18 311:6,6,7,8,8,24 Reporting (2) 5:14,16 reports (6) 26:15 33:5 34:20 41:21 306:11,12 repre- (1) 264:12 represent (5) 6:11 258:19 264:13 266:10 296:4 represented (1) 295:22 reprocessing (2) 269:13,20 request (2) 196:6 280:7 requesting (1) 27:1 requests (1) 304:24 require (3) 148:12 149:4,21 required (1) 183:21 requirements (1) 56:1 requires (2)	150:2 269:16 research (6) 39:3 40:4 163:12 164:13 258:18 315:7 reserve (1) 216:5 residual (3) 174:16 175:21 179:23 resistance (3) 161:6,8 269:17 resistant (1) 192:14 resource-intensive (...) 55:11 respect (3) 21:19 116:3 139:8 response (3) 17:25 21:15 132:23 responsibility (1) 136:14 responsive (3) 110:25 113:10,15 rest (1) 106:13 result (8) 40:18 41:13 84:3 122:11 159:2 160:18 207:5 309:17 resulted (3) 39:6 247:16,18 results (16) 25:8,10 31:23 84:1,2 84:18 92:20 194:25 217:20 222:8 247:24 255:17 282:12 299:19 300:7 301:7 resume (3) 136:19,20,24 retained (1) 10:10 retention (1) 10:12 retracted (6) 127:1,3 128:2 130:4 131:18 314:8 Retraction (1) 314:7 reusable (2) 266:15,16 revealed (3) 126:15,16 239:12 review (79) 12:3 15:3 19:15,18	21:2 22:4 25:2 28:16 29:1,2,14 30:5,13 31:4,7 35:12 36:11,12 37:1 37:22 38:20,23 40:4 43:19,23 44:5,6,13 44:19,20,24 48:2 50:12 52:10,21 54:19,22 55:4 56:24 57:15,20 59:17 62:10,11,14,23 65:23 67:2 69:4,17 69:20 70:8,23 76:13 76:14,17 84:19 88:16 125:24 126:5 127:7 129:2,7,18,18 129:20,25 130:5 134:9 137:3,13 147:25 149:14 187:25 263:25 275:2 280:1 282:6 288:8 reviewed (45) 19:12 26:10,21,22,24 27:6,8,10,18 32:10 32:14,17 34:19 41:10,11 42:4 43:9 46:1,4 47:12,24 52:16 55:6,18 61:16 68:22 69:1 72:19 108:1 117:15 139:13,21 142:4 143:22 146:3 164:18 192:8 198:13,21 213:21 258:12 264:21 294:10 304:1 313:5 reviewers (4) 128:22 149:5,10,23 reviewing (8) 11:7 21:8 36:15 38:5 38:5 39:8 52:24 185:16 reviews (21) 35:14 58:6 59:10,21 62:2 63:1,6,17 64:3 64:9,16 65:24 67:4 67:22 68:2 77:13 79:21 169:20 182:11 202:1 271:13 revised (2) 55:18 56:10 revising (1) 23:1 revision (4)	38:1,4 53:6 68:15 revisions (2) 20:1 52:17 reword (2) 24:9 63:22 right (371) 7:8 10:18 12:19,22 13:8,21 14:3,7,11 14:22,22 15:3,6,11 18:24 19:9,16 21:9 22:18 24:14,15,18 25:6,20 26:18 29:21 30:16 31:2 34:6,7 34:20,23 37:3,4,9 37:15,18,22 38:12 38:16,20,23 39:2 42:24 43:20 44:15 44:16 45:2,9,12,16 45:23 46:2,15,18 47:4,5 50:15,19 51:14 54:1,10,13,17 54:23 57:12 60:8 64:4,20 65:6 66:18 66:21 70:2 71:12 72:11,23 73:12 74:6 74:8,11,12,21 75:2 75:3,4,7 78:25 79:11,14 81:11,13 82:6,17 89:12,17 90:8,10 91:22 92:10 97:22 98:17 100:3 100:21 101:6 103:24 111:14,20 111:25 112:15 114:13,19,24 116:14,24 117:15 118:1 119:9 120:25 122:16,22 123:2,10 124:13,16,21,24 125:7,10,18 126:6 126:11 127:5,14,17 127:23 128:24 129:9 130:16,21 131:17 132:22 139:14 142:6,9,20 147:13,16 151:2,6 152:17 153:25 154:10 155:3,3,6,7 156:20,21,23 158:16 159:5 160:3 160:8,20 161:21 163:20 164:2,16,22 165:9 166:16,17 167:17,20 168:1,8 169:10,10,10,23 171:21 172:10,15
---	--	---	--	--

176:20 178:10 179:4,5 180:17 183:12 184:12,21 184:22 185:25 186:9 190:25 191:21 192:10,11 193:17,19 194:8 203:11 204:7 205:5 205:7,10,14,15,17 206:16,21 207:1,2,3 208:17 209:10,15 210:17 212:8 213:14,21,24,25 215:15 217:9,12,14 217:21,24,25 218:2 218:3,4,7,9,10,12 218:13,15,16 220:4 220:5,7,10,11,13,14 220:16,17,19,20,23 221:1,2,4,5,8,9,10 221:11,13,14,17,18 221:21,24,25 222:2 222:6,9,10,14,18,19 223:20 224:5,12,17 225:2,10,23,24 226:18 227:13,19 227:20,22,23 228:1 228:7,8,10,12,15,16 228:18,25 229:6,11 229:20 230:1 231:5 231:12,13,17,18 232:20 233:7 234:21,24 235:16 237:11,18 238:13 238:17,22 239:22 239:24 240:22 241:8,12,22 244:23 245:2 247:8,9 249:9 249:14 250:5 253:25 256:12,13 256:16 257:5,5,10 257:19 260:8 262:9 262:16,23 266:1,16 266:22 267:9 269:7 272:11,12 280:8,11 280:15 285:22 287:1 288:13,16 289:20 290:11 292:5 293:3 296:8 300:11,25 301:16 301:18 306:5,7 307:11,21 309:14 310:2,3 right-hand (2) 166:11,11 rights (1)	216:5 rinses (1) 297:11 risk (40) 46:24 53:13 69:7 72:7 99:10 109:20 110:14 114:21 121:4 151:12,20,20 152:1,7 153:10 169:11 170:23 171:8,21 174:15 176:16 178:6 180:11 183:23 185:17 187:3 188:2 190:17 197:18 215:14 219:7 231:4 233:13,24 239:13 242:7 250:1 266:19 303:22 314:22 robust (1) 283:10 robustness (1) 279:7 role (6) 16:11 157:6,8 168:25 170:7 182:3 room (50) 42:19 49:25 50:5,7 86:4 106:4,8 109:17 109:19 155:16 160:2 177:5,6,20 185:9 218:11 219:2 220:10 223:23 224:4,8 225:7 227:13 231:23 238:10 241:2,3,3 248:1 249:7,8,10,16 250:4 256:15 262:15 264:17 265:22 266:4,6 272:18 273:16,19 274:9,21 283:23 284:23 300:24 307:18 308:3 rooms (6) 49:23 107:1 219:9 224:9 226:13 307:15 roughly (1) 211:4 route (1) 184:15 routine (1) 122:7 routinely (2) 102:10,12	RPR (2) 1:23 311:23 rule (2) 49:6 231:1 run (3) 286:7,8 291:22 RyMed (2) 124:23 125:2 <hr/> S <hr/> S (1) 3:1 S-Q-U-A-M-E-S (1) 177:9 S-T-E-V-E-N-S (1) 197:24 safe (4) 159:14 245:7 246:22 246:23 safety (3) 34:10 121:2 287:4 Samet (6) 14:21 15:10 16:7 281:15,20 306:12 Samet's (4) 15:17,19 281:7,14 sampler (1) 101:3 samples (1) 92:4 sampling (7) 92:18,19 100:21,24 100:25 101:2 313:7 San (6) 1:17 2:6 5:1,12 277:20,22 satisfied (2) 156:17 157:11 saw (14) 31:25 81:2 101:9 103:23 104:16 106:9 117:12 131:6 201:3 202:8 210:24 258:13 281:10 295:18 sawing (1) 103:2 saws (6) 101:20 103:1 104:23 105:17 106:8 107:8 saying (42) 22:8 29:25 30:22 54:21 64:15 91:15 91:16,16 92:20 104:13 109:1 116:16 123:14	138:22 150:16 162:10 165:6,13 168:4 180:9 214:25 223:6,9 236:10 237:25 238:4,5 241:11 249:23 254:22 263:14,20 263:20 273:1 279:24 284:24 291:3,4 292:4,4 294:25 296:1 says (35) 19:25 48:3 58:18 62:1 69:19,23 71:7 72:1 84:23 88:22 91:4 111:9 127:15 155:5 162:25 165:5 205:18 247:13 263:11 264:24 265:2,2 267:4 269:12 270:2,12,24 271:2,7,8,12,23 272:25 274:6 297:2 scalpel (2) 101:8 105:6 scalpels (1) 101:11 scattered (1) 202:19 scheduled (2) 137:23 144:18 science (13) 13:19,23 14:7 16:16 127:17 128:5 129:8 129:22 130:6 284:14,19 285:5,7 scientific (10) 23:19 25:3 27:23 109:9 129:2,7 147:15 154:13 302:22 306:15 scientists (1) 125:25 SCIP (1) 156:2 scope (1) 203:13 score (10) 59:15 214:18 215:10 216:10 225:9,18,23 226:2 228:14 285:2 scores (1) 230:11 scoring (1) 226:20 Scott (1)	309:13 scowl (1) 251:22 screen (4) 121:12,15 123:18 195:17 screening (14) 118:1,25 120:25 121:20,21,22 123:8 123:18 171:14 195:10,13,14 196:3 313:20 screwdriver (1) 284:4 scrub (1) 231:22 Seal (11) 76:3,4,14 86:12 89:9 89:10,15,18 91:1,10 93:9 Seals (2) 89:9 91:17 Sean (2) 4:12 5:14 search (14) 35:16 37:2 39:3 40:11 41:14 52:14 61:25 63:6,17 70:24 108:10 139:25 157:22,23 searches (20) 35:17 37:2 39:5,7,9 39:10 40:11,18 41:2 41:17 42:1 44:8 62:1,6 104:2,20,21 105:17 140:9 303:16 searching (2) 38:5 52:24 seats (1) 302:7 sebaceous (4) 172:14 173:12 174:4 179:24 second (19) 21:10 26:15 36:22 61:25 86:16,17 96:12 118:12 145:22,23 170:21 193:2 214:12 247:17 248:8,9 267:8 277:11 286:19 secondarily (1) 31:10 secondary (5)
--	---	--	---	--

168:20 251:16 253:18 293:25 297:15 seconds (3) 247:15,18,20 section (5) 28:3 61:24 70:13 198:6 268:10 sections (1) 260:24 secunded (1) 132:5 see (75) 26:10 36:9 38:8,12 45:8,15 53:22 57:2 57:17 70:4 79:19 81:5,5,6 84:22,23 87:1 89:13 107:24 118:18 127:22 129:17 145:15 148:6,7,9 150:15,24 153:15 163:12 164:14 166:8 168:20 182:1 185:21 189:4 190:22 192:1 193:4 193:5 196:15,22 198:20 205:18 208:13 211:16 216:25 223:3 227:16,25 229:19 237:23 239:9 240:25 245:18 248:9 249:5 258:8 260:6 261:8,14 264:24 265:1,6 267:1 274:6 278:23 281:14 286:23 287:24 290:14 295:18 296:21 301:8 302:21 seeding (12) 166:7,14,18,20 167:1 167:6,6,11,23 168:5 169:4 170:2 seeing (4) 36:11 140:7 219:20 261:12 seek (1) 279:14 seemingly (1) 229:13 seen (40) 35:2 61:4 94:19,20 104:6,13,14 107:6 107:11,20 108:5	126:21,23 130:24 140:22 157:24 200:16 210:9 219:19 236:2 240:18 251:18 254:5 258:6,22,24 260:23,24 283:14 283:18,22,22 284:19,20,23,25 285:1 298:12 301:20,23 seeps (1) 174:3 sees (2) 113:25 116:7 select (1) 35:11 selected (2) 70:11 143:10 selection (4) 265:3,8 266:11 315:11 selective (3) 122:2,2,9 Seminars (5) 157:4 158:1 163:5 182:2 314:17 send (2) 203:23 232:25 senior (1) 129:3 sense (5) 58:25 63:25 121:19 241:1,4 sensitive (1) 92:4 sent (5) 17:25 35:13 132:20 135:2 282:6 sentence (22) 86:17 88:8,18 92:1,24 154:3,16,17 155:4 166:5,5 167:10,11 168:3 170:21 182:2 248:2 268:19 271:15 296:21,22 297:3 sentences (2) 88:15 166:6 separate (2) 285:4 299:14 separately (3) 19:20 32:8 96:13 series (11) 118:10 227:16,21 229:18 231:11	304:10,10,16 308:11,24,24 serious (3) 212:19 243:11,19 serve (1) 253:18 served (1) 19:4 Service (1) 201:10 services (1) 156:1 Sessler (5) 143:19 144:3 304:22 304:25 305:3 set (9) 8:14 219:10 241:11 284:3,20 285:9 302:16 311:12,19 setting (2) 93:19,20 settings (2) 121:2 314:6 setup (2) 22:18 304:13 Seventh (1) 4:6 severity (2) 215:4 231:15 sex (1) 214:2 share (1) 129:18 shared (3) 25:11 119:13 265:3 shareholder (1) 81:19 sharing (1) 265:14 Sharp (1) 33:23 shaving (1) 221:10 sheet (3) 179:15,20 316:1 shifted (1) 157:17 short (4) 49:3 108:16 111:22 234:22 short-term (2) 234:8,18 short-time (2) 233:10,21 shorted (1) 289:18	Shorthand (3) 2:7 311:5,24 shortly (1) 140:8 show (41) 6:19 8:13 46:21 47:9 57:3 58:20 60:21 72:3 75:13 94:20 95:20 97:14 99:5,13 100:2 105:15 107:12 109:17 110:7 113:12,17 123:21 125:4 126:18 132:14 139:18 162:17 169:16 190:16 192:4 204:21 235:25 244:11 258:4 260:20 266:9 268:15 281:1 298:6 299:19 301:12 showed (16) 81:1 88:25 92:16 96:3 96:21 111:14 112:16 114:23 119:17 175:17 196:1 237:9 252:5 269:1 295:13 299:19 shower (1) 160:13 showing (16) 58:25 68:17 84:4 86:8 86:12 118:6 120:22 121:9 169:8 197:2 297:10,14,15 304:13,23 305:5 shown (12) 91:4 93:16 105:8,9,11 120:16 121:18 158:22 251:13 254:20 255:3 296:18 shows (10) 80:7 83:15 86:18 158:2 171:7 251:3 253:17,20 268:16 298:21 sic (9) 7:22 16:21 63:15 78:16 91:17 180:25 197:15 225:4 261:3 sick (1) 144:22 sicker (3) 215:8 225:12 230:7	side (5) 175:5 231:7 247:13 249:9 266:18 side's (3) 133:1,22 134:6 sign (1) 310:2 signal (1) 209:8 Signature (1) 316:21 signed (3) 7:3 128:23 138:15 significance (1) 188:15 significant (14) 78:25 79:8 81:3 86:18 111:10 119:18 196:2 217:11 223:5 227:7 237:10 239:12 240:2 241:6 significantly (3) 114:10 121:10 295:3 signs (1) 214:25 Sikka (3) 34:4 68:22 69:17 similar (11) 28:22 71:7 147:8 159:11 245:1 246:13 247:2,5,9 258:25 288:24 similarity (1) 247:8 Simmons (5) 209:17 222:22 224:6 225:3 237:13 simple (2) 110:15 113:9 simpler (1) 229:10 simulate (1) 299:8 simulated (3) 299:15 300:23,24 simultaneously (2) 81:11 82:10 single (20) 56:13 93:6,22 94:12 96:14 98:5,9,20,21 100:2 105:5,18 149:8 160:16 252:4 276:9 289:1 292:3,3 295:22 single-point (1) 92:18
---	--	--	--	---

7:9 8:20 26:11 78:23 94:7 109:24 110:23 113:9 244:10 278:7	skill (2) 212:7,11 skin (38) 42:18 154:20 156:7 164:2 170:22 171:2 171:6 172:7,10,23 173:23 174:5,17 175:2,20,22 176:3 176:10,12,15 177:3 177:9,13 178:5,17 179:2,3,4,17 180:8 180:10,15 186:25 196:9 221:1 289:3 292:25 293:1	someday (1) 56:8 somewhat (6) 126:14 137:6 139:11 188:16 208:8 276:15 Sommerstein (4) 244:14 245:16 247:11 249:3 Sonner- (1) 247:10 soot (30) 251:11 288:12,18,20 289:5,7,11,19,22 290:7,14 291:1,6,8 291:13,15 293:3,8 293:11,17 294:2,13 294:17,23,24 295:11,18,22 296:4 297:13 Sorin (1) 246:6 sorry (27) 7:7 33:21 64:11 74:25 85:5 86:22 90:25 112:1 115:24 136:18,21 145:1 148:18 160:11 166:5,12 167:8 169:18 176:9 207:2 208:3 215:23 233:16 234:4 239:16 267:19 296:25 sort (4) 21:4 133:21 210:13 276:8 sorts (2) 203:22 285:11 sound (4) 10:1 25:20 39:1 206:15 sounds (2) 143:2 309:3 source (33) 41:8 151:15,17 152:19,20,20 153:5 153:7 154:19 155:15 160:22 162:1 163:25 166:17,22,24 168:10 169:6,12,13 170:4,13 171:3 177:23,24 186:4,15 201:1 203:11,25 204:2 245:15,24	sources (29) 151:19 152:16 153:4 153:11 154:5 157:3 157:8,12 158:5 162:9 163:1,9,18 165:6,8,13,13,18,22 166:13 170:20 181:22 182:20 185:20,25 204:18 204:18 224:22,22 South (2) 3:6 4:6 space (1) 257:1 spans (1) 137:17 speak (4) 259:22 263:5,24 264:18 speaking (6) 72:15 115:5,20 116:17 263:9,10 speaks (3) 48:10 72:13 279:25 Spear (2) 2:6 5:12 specialist (1) 5:15 species (1) 178:18 specific (51) 16:14 36:9 44:9 50:2 50:8 53:8 59:19 61:12,21 62:14 68:13,14 71:3,15 73:21 90:1 95:17 96:16 123:17 126:23 137:9 143:13 145:11 148:4 153:19 157:10,24 158:19 165:25 182:1 188:8 191:6 202:21 203:7 203:10,10 217:8 218:11 226:1 233:9 233:21 234:7 238:8 240:9,12 241:16,18 242:8 264:9 266:4 284:1 specifically (43) 17:5 36:11 37:21 38:22 43:2,14 49:2 52:18 56:20 65:12 67:11 69:22 71:19 72:14 83:20 92:8 94:19 95:2,5 98:15	105:25 122:19 133:7 152:11 166:2 167:13 170:7 183:4 184:2 191:20 200:6 204:6 257:2 259:23 267:4 270:19 274:6 283:24 287:2,8 304:12 307:9 308:23 specifics (1) 53:2 spectrum (1) 173:18 speculated (1) 293:20 speculating (2) 264:19 294:6 speculation (4) 159:7 160:22 230:17 294:9 Speculative (1) 230:18 speech (1) 268:22 spell (1) 76:7 spent (6) 19:3 22:25 38:4 40:3 227:11 283:18 spewing (1) 103:23 spews (1) 108:22 spoken (1) 123:5 spread (4) 168:15 184:6,7,14 Spreadsheet (1) 314:18 squame (2) 289:3 293:1 squames (2) 177:9 292:25 squared (1) 50:4 SRs (3) 62:2,3,7 Ss (1) 311:2 SSI (14) 46:25 72:7 155:15 165:21 169:6 170:5 171:11 172:3 197:18 206:7 216:19 239:13 286:22 303:21
---	---	--	---	---

80:17 81:4 85:25 86:5 112:24 113:1 152:17 154:5,18,19 156:19 157:3,18 163:1,19,25 165:5,8 165:23,25 166:3 168:6,7 181:23 206:8 staff (5) 15:17,20 55:4 183:24 227:12 standard (18) 28:9 30:1 31:3 43:19 44:22 45:5 49:24 50:13 51:23 54:23 64:22 65:3,3,4,15 164:11 185:14 276:13 standard' (1) 28:4 standards (2) 66:24 313:19 standpoint (1) 23:19 Staph (37) 159:19,24 160:3,9,17 161:1,5,11 162:17 168:18,18 174:11 174:16 180:25 185:5 192:12,15,17 193:7,8,11,13,20,23 194:16,19 195:3,8 196:13 202:9,12,22 251:14 287:13,16 290:21,23 Staphylococci (1) 202:23 staphylococcus (12) 8:1 194:21 255:22 256:4 287:25 288:9 289:1,8 292:19,20 292:20 313:21 start (12) 5:5 8:21 26:15 45:14 51:5 67:5 76:14 150:20 182:21 203:22 221:20 236:21 started (7) 130:20 154:1 155:21 164:5 236:17,22 274:14 starting (7) 5:18 7:6 160:19 182:23 221:17 247:12 248:1	starts (2) 7:17 266:13 state (5) 156:18 257:16 277:18 311:2,9 stated (1) 306:2 statement (9) 65:1 93:4 143:17 164:20 169:3 170:2 180:16 265:20 274:8 states (8) 1:1 5:8 49:25 107:2 176:24 246:3 276:23 277:4 statistical (7) 86:18 131:12 188:15 189:4 227:16 229:19,23 statistically (6) 78:24 79:8 189:5 237:9 240:1 241:6 statistics (5) 127:13 129:6 130:18 130:25 143:3 status (4) 214:10,13 216:9 239:21 stay (2) 239:15,19 stayed (1) 226:15 step (1) 45:21 sterile (11) 94:5,21 96:4 106:6 146:25 155:18 197:10 246:15 256:18 297:17 303:19 sterilization (1) 106:18 sterilized (4) 106:4,8,17 107:3 steroids (1) 217:23 Sterums (1) 197:21 stimulate (2) 269:18,19 stipulate (3) 10:4,8 41:18 Stocks (21) 72:11,14,23 73:7,9 74:20 75:6 76:5	77:7,12,17 81:18,21 81:24 82:12,23 83:14 89:11,11,18 91:1 Stonington (3) 17:9,15 144:13 stop (6) 102:14 115:6,8,17,20 214:12 stopped (1) 188:6 straightforward (1) 142:18 stratified (1) 232:16 streams (1) 256:5 Street (3) 3:6,13 4:6 strike (27) 46:11 75:23 109:22 110:22 113:7 115:5 140:21 149:18 177:25 179:2 187:19 193:9 202:10 210:5 217:17 229:2 246:24 248:18,20 248:22 251:17 254:17 280:5 294:1 298:15,18 300:20 string (1) 315:14 strong (1) 237:14 stronger (1) 93:19 strongly (2) 210:15 215:13 stuck (1) 210:20 studied (1) 158:25 studies (105) 12:10 20:15 21:16,25 22:7 30:7,8 43:7,15 43:15 46:20 58:12 58:13,15,16 59:3,4 59:8,10,11 60:8,11 62:4 63:15 65:10 72:2,3 73:11,14 75:16,17,19,21 80:21 90:1,7,9 94:20 95:3,7,11,13 96:3,16,21 97:14 98:8,13,15 99:13,17	100:1 104:6,14 105:21 107:6 108:24 109:14,17 110:7 120:22 121:9 146:22 153:12,14 153:16 175:2 176:3 185:17 188:1 197:9 197:11,13 215:20 219:19 231:25 250:13,19,21 251:7 251:13,25 252:15 252:24 253:1 254:1 254:5,16,20,24 255:2 257:15,21 290:18,22 291:5 296:18 297:6,10,10 297:15 304:11,14 304:22 305:4 study (166) 20:1,3,4,11,20 21:2,3 21:3,8 22:5,16 24:7 24:13,16,21 25:7,9 25:10 31:11,12,16 31:17 34:12 43:5,6 48:6,16 49:6 51:2 58:4,8,8 75:6 77:7 79:12,13,15 80:10 80:14,15,15 81:5 82:4 83:1,19 84:2,4 84:6 88:15 93:10,16 93:22 94:12,19 97:18,25 98:3,5 100:17,20 108:11 111:2,7,14 112:15 112:21 113:2,4,12 113:17 114:2,5,23 116:10 123:22 124:15 125:16 127:13,14 142:3,5 142:11,14,17 146:1 154:23,25 157:16 164:12,14 169:24 175:14 178:15,16 178:19,19,20 186:14 189:7,10,22 190:8,15 191:12,13 191:22 192:10 200:4 205:23 208:1 208:17 209:2 210:13,23 212:6 213:22,24 215:11 216:8 217:10 231:23 233:9,9,11 233:15,20,20,23 234:1 235:19 236:12 238:21	239:24 240:4,5 245:20,21 251:3,11 251:18 252:4 253:17,20 254:10 254:14,15 257:3,16 278:22 279:3,5,7 282:15,22 287:1 297:6 299:13,14,15 299:18 304:25 305:4,6,7 309:13,15 stuff (5) 8:10 115:25 130:19 199:16 203:22 subcontracting (1) 55:24 subject (2) 35:5,9 submission (2) 147:21 282:18 submit (3) 148:12 149:22 282:12 submitted (6) 149:7,9 300:5,18 304:7 308:13 subpoena (1) 27:2 Subscribed (2) 310:8 316:22 subsequent (2) 19:2 25:22 subsequently (1) 32:7 subset (2) 136:9,14 substance (5) 13:24 14:4 20:7,11 134:20 substantially (2) 209:9 290:15 substantiate (4) 27:21 42:23 43:1 44:2 substantiating (1) 42:13 substitute (1) 112:10 sued (1) 128:10 sufficient (3) 176:6 249:18 251:16 sufficiently (1) 216:23 suggesting (1) 294:15 suggestions (4) 52:17 55:7 265:15 271:20
--	---	--	--	---

suites (1) 283:20	209:13,21,24 210:2 210:17,19,21 211:7 211:15,25 212:7 221:13 223:1,12 224:25 225:5,6,8 226:16,22 228:5,7 230:1,2,3,3,5,25 231:21 232:5,7,20 235:20 237:8,9,15 237:17 241:24 242:14 299:24	156:2,3 158:3,10,14 158:24 159:25 160:17 171:5 173:25 175:2 177:15 178:22 181:25 212:7,11 219:14 231:3,15 246:15,16 247:18 283:20 286:21 287:6 299:8 305:17 305:20 308:2 313:10,13	316:22 system (15) 59:7 81:13,20 82:5 89:1 92:4,9,17 111:10 121:15 190:5 219:5 303:12 307:21 315:6 systematic (36) 29:1,2 30:12 31:4,6 43:19,22 44:5,6,13 50:12 54:19,22 58:5 59:10,21 62:2,10,11 62:13,25 63:6,17 64:3,9,15 65:23,24 67:2,4,22 68:1 69:3 69:17 70:23 84:19 systematically (1) 53:16 systemic (1) 70:8 systems (8) 2:12 121:17 183:21 183:22 184:1 275:24 307:10,11	takes (3) 83:8 257:15 277:12 talk (34) 29:4,21 32:8 34:23 36:21 42:16 46:14 51:5,22 59:13 71:19 117:18 121:20 123:17 165:2 166:6 182:19 184:4 187:8 187:16 195:12,13 217:17 250:25 269:22 270:8,15 271:1 285:3 292:19 294:1,2 296:17 297:4 talked (14) 45:5 72:20 104:22 134:21 142:2 150:8 183:4 185:15 186:24 189:7 228:15 239:8,8 250:14 talking (68) 28:21,25 29:13 34:6 41:22,24 42:17 66:14 67:11,12 93:5 96:21 99:7 104:9,10 105:7 107:2 110:13 110:18,19 151:11 160:9 163:7 165:1 166:2,3,14 167:13 168:12,16,24 170:9 176:4 179:23 180:14 182:13 183:25,25 190:12 191:21 197:15 201:13 224:12 249:13 255:1 258:15 263:2 272:5 272:6,23,25 273:10 273:10,15,17,21 277:1 287:3,7 288:25 289:24 290:7 292:11,12,15 295:17 299:12 300:6 talks (8) 58:7 155:14,14 183:14,17,19 184:13 270:18 Tande (1) 34:4 targeted (2) 121:5,13 TB (1) 183:5
summary (2) 28:3,3				
superficial (2) 81:3 206:8				
superior (2) 175:13,18				
supervised (3) 51:21 52:13 153:22				
supplement (2) 61:3,12				
supplementary (2) 61:9 313:15	surgeon's (5) 225:2,2,20,21 230:5	surprise (1) 150:13		
supplies (1) 224:14	surgeon-specific (10) 211:13,15,21 212:13 213:9 215:12 222:24 229:15 286:22 287:1	surrogate (3) 75:22 91:22 92:10		
support (16) 27:21 44:11,14 45:1 45:15 75:21,25 93:4 93:8 141:16 146:23 169:3 170:1 287:20 288:8 294:4	surgeons (12) 196:7 198:1 210:10 210:22 211:1,3,8,12 220:13 225:11 226:15 237:11	surrounding (1) 257:1		
supported (1) 45:1	surgeries (2) 108:14 229:13	surveillance (22) 42:19 121:6 122:22 190:3,4,5 201:18,20 201:22,23,24 202:1 209:19 236:7,18,24 237:1,4 287:3,5,8 303:12		
supporting (2) 61:1,2	surgery (35) 67:25 69:22 101:12 101:17 102:11 107:17 109:1 110:17 112:24 114:7 159:17 172:23 175:23 177:11 210:6 214:7 214:21 215:9 216:21 219:22 221:20 222:5 232:14 239:14,16 239:18 245:6,10,11 245:19 278:16,17 299:15 313:24 315:5	surveillances (1) 236:20	T	
supports (5) 93:10 141:14 147:7 147:12 250:16		survey (2) 204:6 210:9	T (2) 131:7,10	
supposed (1) 308:12		surveys (1) 203:18	T-S-A-I (2) 96:7,8	
supposes (1) 295:11		susceptibility (1) 161:12	table (15) 86:8 115:2,14 116:24 117:2 152:9 167:19 177:20 216:14 249:10 250:4,5 256:15 285:22,24	
sure (48) 9:7 12:1 13:25 14:17 21:12 24:10 29:6 33:7 34:5,21,22 69:13 82:1 88:17 98:17 101:23 111:25 132:1 133:25 134:1 136:15 139:25 140:1 141:1 145:5 152:5 157:24 163:6 163:11 164:17 174:2 191:8 197:20 200:15 204:16 208:1 210:24 223:12 230:6 232:12 243:12 258:15 279:13 284:22 285:1,5 288:21 299:2		susceptible (1) 192:13		
	surgical (81) 35:19,22,25 42:19 50:25 51:11 53:4,8 54:20 56:11,17 57:11,11 60:18 63:4 63:14 64:19,23 65:5 65:12,14 66:25 67:7 67:10 68:9,15 71:2 80:25 81:7,8 86:1,3 93:24 94:15 96:23 99:15 104:16,23 105:4 108:12 111:4 111:16,23 112:18 113:20 114:6 147:2 153:2,23 155:16	suspect (2) 290:24 291:6		
		suspected (1) 209:24	tailored (1) 188:7	
		suspended (1) 255:10	take (28) 27:10 43:25 47:22 60:18 69:11 75:5 111:6 116:4 118:21 131:21 133:24 138:22 146:20 159:24 160:12 161:15 180:22 181:5 187:12 202:9 213:16 230:3 243:23 247:10 297:19 300:2 302:2 302:20	
		swabbing (1) 297:11	taken (10) 77:1 132:8 159:20 181:13 244:1 270:5 271:4 278:10 284:4 297:24	
		swabs (5) 121:22 254:25 255:1 257:24,25		
		swear (1) 6:3		
		switch (2) 236:14 302:6		
		switched (2) 196:13 238:16		
		Switzerland (2) 118:18 245:17		
		sworn (4) 6:5 310:8 311:13		

team (3) 14:22 15:11,13	testified (1) 6:5	259:12 261:1 276:2 286:2 289:5 301:4	211:24 212:18 223:25 225:4,7,25 231:19 232:19 239:2,7 243:18 249:4,10 250:1,13 254:18 257:24 260:24 261:23 262:1 266:4 272:3 273:9 274:13 275:9 276:7 279:1,8 284:16 293:21 296:1,10 297:9 298:14 299:10 300:14 301:2,4,23 302:4 308:1,4	70:15 76:24 77:4 85:7 101:8,14,15 102:15 111:6 118:21 120:1 132:6 132:11 137:25 140:9 144:5 153:22 158:7,9 169:10 173:12 181:11,16 188:23 200:3 205:9 216:6 218:14,17,24 219:17 222:4,11,12 226:5 227:6,12,12 234:22,25 235:3,6 236:6,17 238:13 240:18,20 243:16 243:24 244:4 246:7 259:10 283:19 287:24 297:22 298:2 303:10 309:23
technically (1) 78:24	testify (1) 211:20	things (52) 19:24 29:1 32:9,18 44:1,14,25 47:2 49:16 55:24 105:22 108:25 109:25 117:22 120:12 123:7 155:13 157:17 164:15 171:20,23,25 172:2 176:14 181:24 197:6 198:11 204:11,12,17,17 209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	thinking (7) 140:11 223:18 224:3 254:10 269:18,19 300:4	timeline (1) 186:22
technique (3) 187:1 230:5 231:15	testifying (2) 274:2 279:23	108:25 109:25 117:22 120:12 123:7 155:13 157:17 164:15 171:20,23,25 172:2 176:14 181:24 197:6 198:11 204:11,12,17,17 209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	third (4) 91:3 199:19 217:14 296:16	times (25) 64:12 71:5 125:16 158:22,25 203:19 208:10,16,23 210:19,19,21 212:15,18,18,20,24 212:25 213:3,10 219:16 225:22 244:7 260:12,13
Technologies (2) 124:23 125:2	testimony (23) 7:16 43:8 60:2 68:11 83:24 94:2 103:13 134:17 142:8 162:14 174:22 193:14 195:16 212:2 237:20 238:3 267:15 270:20,23 302:14,17 308:7 311:14	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	tips (1) 107:8
tell (33) 9:16 11:14,15,24 27:14,14 33:11 40:23 47:23 51:9 75:19,24 76:16 95:19,19 98:20 105:18 107:23 134:24 149:10 183:13 199:5,11 205:22 213:14 242:1 250:16 258:9 264:22 275:1 279:12 282:5 291:16	testing (7) 122:11,24 123:1 259:17 260:5 308:23 309:9	think (146) 7:17 10:7 15:17,25 19:10,14,17 23:25 29:24 30:9 32:15 33:14 34:22 35:9,19 39:15,20 40:6 45:22 46:6,10 48:4,21 49:15,16 50:1,11 53:7,10 56:19,21 59:7 70:7,25 81:4 86:20 88:20 94:9,18 95:4,10 108:17 109:8 111:24 117:11,12 118:12 123:8 125:24 128:14,17,20,23 130:10 131:7,11,15 140:8,16,24 141:1 141:10,21 143:16 144:4,9 145:13,23 145:24 146:7,21 147:2,5 149:2 150:1 153:12 160:24 165:20 168:24 170:6 172:4 174:23 176:1 180:13 184:9 186:21 188:12 194:18 195:10,20 195:20 198:1,12,16 198:16 199:1 200:14,15,22 201:20 204:12 207:13,15 209:11	thought (22) 47:13 64:2 85:3,7 110:19 130:9 159:13 200:12 202:16 210:24,25 215:3 219:21 224:23 229:17 241:18,21 245:13 246:22 281:4 282:8 282:21	timing (3) 186:25 188:8 220:24
telling (2) 134:2,6	Texas (3) 3:21 289:17 293:13	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	titled (19) 313:2,5,6,10,12,15,16 313:20,23 314:3,7 314:12,14,17,22 315:3,8,10,12
tells (1) 162:10	text (1) 267:3	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	tissue (2) 102:3 110:17
tend (7) 49:23 56:22 148:4 215:7 292:4,6,20	textbook (3) 157:1,15 287:24	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	tissues (2) 170:22 180:11
tends (1) 188:7	textbooks (1) 287:22	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	title (1) 35:4
Tennessee (7) 234:13,15 235:20,25 237:6 238:21 241:22	Thank (4) 180:20 265:10 296:25 306:23	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	titled (19) 313:2,5,6,10,12,15,16 313:20,23 314:3,7 314:12,14,17,22 315:3,8,10,12
tenure (1) 155:9	Thanks (1) 301:25	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	today (9) 187:8,12,13 211:19 244:7 260:23 264:15 302:17 309:8
terminate (1) 115:25	theaters (2) 48:6,17	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	told (9) 11:3 131:15 133:8,9 133:13,22 134:17 135:2 308:14
terms (31) 20:10 31:2 35:9 38:14 50:18,24 52:20 56:24 63:3,13 68:18 78:1 112:22 123:5 151:12 168:17 190:2,18 194:13 212:14 214:23 225:17,20 280:4 284:5 285:21 288:25 294:10,11 303:21 304:2	theatre (7) 86:17 87:9 88:4,25 91:5,20 92:16	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	tone (1)
test (7) 83:6 90:3 131:8,8,8 131:10,10	theatres (2) 313:8,18	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	
tested (1) 308:17	theatrics (2) 109:5,7	209:4 211:11 213:8 213:13,17 220:1 223:13,16 224:15 227:10 231:20 232:10 233:4 240:15 241:12 243:8 261:9 272:10 272:11 285:11 302:15	THOMAS (1) 3:3	

251:22 tons (1) 179:18 tool (2) 102:5,8 tools (1) 155:17 top (8) 115:24 150:20 166:11 199:20 202:17 249:12 258:19 286:20 torn (1) 284:4 total (18) 25:19 38:15,18 39:1 39:25 71:3 80:7 102:15 108:19,19 114:19 194:13 221:3,6 222:11 231:16 314:16,23 totally (2) 115:1 177:2 touch (3) 9:5,7 10:17 tourniquet (1) 221:7 Tower (2) 2:6 5:12 traffic (1) 73:25 training (3) 30:24 303:5,9 transcript (2) 131:25 145:10 transfusion (1) 216:20 transient (5) 92:5 172:12,13 184:24 187:17 transmission (9) 120:18 183:23 184:5 184:24 185:4,7,13 187:17 315:3 transpor- (1) 184:24 tremendous (1) 155:22 trend (1) 114:10 trial (16) 50:20 51:3 56:13 58:5 58:24 67:6,18 80:21 83:15 107:18 113:18 175:9 196:1 275:4 309:20	313:25 trials (33) 54:1,10,17 56:11 58:12 59:9,20 62:3 62:4,25 63:7,8,8,9 63:18,19,20,20 64:4 64:7,9,15 65:18 66:1,9 67:1,5,21 68:1,4,17 80:17,18 tried (11) 45:3,11,17 53:11 70:23 82:13 138:19 224:19 257:21 259:3 293:16 tries (1) 53:3 trouble (1) 181:3 true (13) 72:7 93:17 126:15 151:1 159:9 178:14 215:20 225:15 239:2 279:1 291:25 293:25 311:13 trump (1) 203:17 trusts (2) 201:18,19 try (17) 32:2 44:6,7 45:10 67:14 80:10 131:3 158:19 161:9 188:1 188:3 213:18 240:13 259:18 260:16 265:9 303:13 trying (37) 17:12 29:19 30:22 32:2,9 39:23 44:9 44:15,24 45:2 53:17 53:24 71:9 94:18 95:10 116:2 118:15 142:1 145:25 153:12 165:20 186:13 193:4 195:18 198:7 200:14 201:2 205:18 217:1 229:12 235:12 240:8 241:16 247:22 249:25 260:15 269:5 Tsai (4) 96:6,12 251:11 253:17 TSG (2)	5:14,16 tuberculosis (1) 292:13 tubing (2) 269:16 270:14 Tuesday (2) 1:18 5:2 Tuimia (1) 33:13 turbulent (5) 92:6,8,15 93:3,19 turbulent- (1) 91:20 turbulently (3) 88:24 89:5 91:20 turn (5) 86:15 121:18 154:14 261:18 286:16 turned (2) 225:14 285:12 turning (1) 284:5 Twenty- (1) 298:9 twice (2) 288:14 308:20 two (63) 7:22 13:15 31:17 34:20 37:8,21 38:22 44:10 48:24 50:2 55:10 61:19 95:17 99:5 124:6 125:23 140:14 145:19,21 149:5,16,22,22 153:25 154:1 175:5 176:5 177:5 178:24 183:25 188:6 189:20 191:12 202:24 205:7 206:7 207:1 210:14 213:19 217:11 226:13,22 229:14 233:4 235:18 239:12 240:10 245:7,11 248:7 257:7,11,17,17 272:10,11 274:7 289:2 304:14 307:22,24 308:21 309:5 two-thirds (1) 199:17 type (24) 57:1 58:9 83:5 111:10 124:12,15 160:18 161:18 188:6 207:4	220:2 233:8,12,14 233:20,23 234:1 238:9 239:13,16,18 245:21 277:3 285:13 types (17) 49:2 58:16 59:8,11,14 59:16 60:4 104:7 122:25 124:6,7 136:12 191:11,14 230:21 235:18 239:13 typical (1) 292:8 Typically (1) 208:11 typing (4) 178:23 185:21 203:4 204:3 <hr/> U <hr/> u (2) 84:25 85:4 U-N-I-V-A-R-I-A-... 216:16 UK (1) 300:18 ultimate (1) 59:15 ultimately (4) 89:18 198:8 217:15 238:19 ultra-clean (3) 86:17 89:1 91:8 ultraclean (8) 87:8 88:3 91:4 92:4 92:17 247:14 248:3 249:19 Ultraclean (1) 315:5 unable (1) 216:18 unanimity (1) 172:21 unanimously (1) 109:9 unaware (1) 128:3 Unbiased (1) 44:19 uncertain (1) 194:3 underbilled (1) 39:17 underestimate (2) 39:12,13	undergoing (4) 165:23 177:4 206:25 239:11 underlying (3) 214:4 243:6 279:15 underneath (3) 71:7 177:20 250:5 underreporting (2) 202:3,4 understand (17) 29:4,19 30:22 39:24 59:19 60:1 66:16 74:1 75:18 142:2 145:25 165:2 180:9 201:2 242:18 280:5 280:6 understanding (19) 6:12 7:2 60:7,24 62:10 63:5,16 106:7 111:5 236:14 240:8 262:20 264:14 283:8,9 287:15 291:1 295:21 309:7 understood (2) 16:11 262:18 undertake (1) 53:6 undertaken (1) 264:6 unfair (2) 116:9 175:7 Unintentionally (1) 22:15 unit (8) 106:10 244:8 245:2 249:6,18 250:22 251:10 256:14 United (7) 1:1 5:8 49:25 107:2 246:3 276:23 277:4 units (11) 48:8,19 50:4 83:17 197:8 244:23 263:3 270:5 274:17 303:17 315:4 univariate (6) 216:14,16 228:6 233:4,6 237:7 Universal (1) 313:20 university (8) 119:14,17 127:8 129:4,21 130:11,14 175:15 unpublished (1) 281:15
--	---	--	--	---

unreasonably (1) 302:25	68:24 259:23 302:18	40:18 41:14 80:7	vivo (3) 21:6,17 304:15	315:12
unrepresentative (1) 116:9	valid (4) 75:22 87:5 88:1 164:14	110:15 119:24 170:14 175:3,4,10 175:17 177:6 179:19 190:17 210:8 225:10,21 232:5 237:8 238:13 242:25 249:14 299:10	Volume (7) 5:5 77:3 132:10 181:15 244:3 298:1 309:22	WarmTouch (1) 255:10
unresolved (1) 58:23	value (5) 43:4 78:6,19 125:24 232:6	242:25 249:14 299:10	volumes (1) 145:19	wash (2) 144:23,25
unusual (11) 149:2 159:11,17 161:2,16,18,24,25 208:9 215:18 244:19	valve (1) 168:14	vertical (2) 119:24 120:1	wait (1) 116:2	Washington (1) 11:15
unusually (1) 207:6	Van (4) 197:15 198:18,20 199:4	vessels (1) 102:4	waived (1) 133:21	wasn't (15) 32:1 72:15 82:8 124:17 130:7 210:20 211:5 223:23 225:15 230:1 235:7,19 239:23 279:21 294:21
unworthy (1) 281:24	vancomycin (2) 161:6,8	vetting (1) 263:25	waiving (1) 13:25	water (22) 219:13 246:10,12 268:8,17 269:8,16 270:3,21 271:9,11 271:21,24,25 272:4 272:4 273:2,22,24 289:17,25 290:1
update (4) 34:10 56:12 57:12 261:5	variable (1) 225:25	viable (3) 250:17 251:2,4	walls (1) 223:23	way (47) 8:10 19:19 24:8,22 25:11 43:11,14 45:6 46:5 52:12 81:18 82:12 84:24 85:15 99:3 101:4,7 102:3 113:24 116:7,8 125:6 128:21 152:15 186:8 203:3 203:6,8 211:9 214:20 215:1 219:20 227:11,24 228:2,9 242:17 249:7,16 263:11 267:3 269:5 270:25 273:23 283:3 286:12 311:17
updated (3) 51:1 57:7 261:9	variables (1) 243:13	vicinity (5) 87:7 88:3 93:24 94:14 299:21	want (59) 6:23 8:9 13:25 21:7 21:15 28:1 29:4,5,5 30:21 32:16 41:7 52:19 61:23 62:17 67:15 84:4 111:24 111:25 115:15,16 116:13,20 118:13 119:25 122:11 134:5 136:25 137:10 146:9 181:7 187:5,11,15 194:9 194:22 204:7,12 216:4 218:18 234:4 234:17 250:25 258:15 259:11 268:21,22 270:16 270:17,19 277:21 285:5 297:4,20 298:12 302:2,5,9,19	ways (3) 55:2 188:3 203:14
upgrade (1) 215:7	varicella (1) 183:5	video (1) 5:15	wanted (3) 190:22,23 247:7	we'll (12) 6:24 8:8 10:7 24:3 32:7 33:4 34:23 76:23 217:14,17,17 266:21
Upper (2) 285:15,16	varies (6) 56:6 263:19 274:25 276:12 288:19 289:4	videographer (14) 4:12 5:4 6:2 76:24 77:2 132:6,9 181:11 181:14 243:24 244:2 297:22,25 309:21	wants (4) 115:13 127:21 181:1 232:25	we're (31) 19:24 44:9 76:25 77:4 83:18 99:7 104:9,10 105:7 107:2 110:18 115:25 132:7 137:6 137:8 151:11 159:11 166:2,3 181:17 187:8,12 216:4 238:9 243:8 249:13 258:15
use (37) 23:24 43:19 69:21 88:14 92:17 101:13 101:13,18 102:17 103:22 104:7,15 111:15 112:16 121:25 122:1,1,7,8 122:9,12 136:3,7 147:18 156:7 171:5 189:14,24 217:23 218:4 220:21 221:7 221:15 236:5 242:25 247:4 308:24	variety (19) 29:14 59:13 121:24 124:18,20 137:17 159:23 185:20 197:7 223:4 229:23 246:2,17 260:5 290:19 291:6 303:16 304:5,19	videotaped (3) 1:16 2:4 5:6	warmer (1) 238:9	
useful (2) 149:15 281:4	various (11) 27:21 35:25 36:3 59:16 60:19 108:16 127:13 197:5 200:1 305:2 314:19	view (6) 44:3,11 50:24 53:7 70:1 120:20	warmers (6) 35:19,22 36:2 71:1 198:4 255:18	
uses (6) 54:23 267:9,12 268:2 269:15,16	vary (2) 242:24 287:12	viewpoint (3) 119:10,11,13	warming (19) 1:4 5:7 69:6,21 111:10 190:18 233:12,23 235:15 235:18 236:5 238:16 239:13 240:10,21 299:22 305:1 314:12	
usually (10) 42:10 101:19 102:9 121:22 188:15 203:25 214:25 249:8 264:11 276:19	vascular (2) 175:11 214:17	viewpoints (1) 119:9		
	velocity (6) 247:16,19 248:17,24 249:1,17	views (1) 264:13		
	ventilated (4) 88:25 89:5 91:20 92:16	vigorous (1) 117:24		
	ventilation (11) 93:3 167:4 184:12,16 184:19,20 219:4 307:10,11,21 315:5	Virginia (3) 119:14,18 175:16		
V	veracity (1) 194:4	virtually (8) 85:25 110:16 128:11 148:25 149:1 168:19 222:19 235:7		
VA (1) 121:15	version (1) 266:11	viscera (1) 154:21		
Vague (3) 24:24 40:5 42:9	versus (22)	visualization (1) 304:3		
vaguely (3)		vitae (1) 7:8		
		vitro (3) 21:3,6,17		

288:25 297:23 298:2 309:23 we've (13) 18:21 94:20 136:12 137:14 149:9 186:24 203:17 213:3 218:24 224:7 228:14 231:2 302:1 website (3) 34:8 147:23 148:2 websites (1) 261:8 week (1) 219:17 weekend (1) 219:3 weeks (5) 132:21,21 140:15 176:4 188:6 Weighing (1) 271:3 welcome (2) 116:11,15 well-established (4) 184:23 185:4,13 187:16 went (12) 53:9 56:23 70:4 125:9 142:2 159:23 196:9 197:25 223:17 237:5,16,21 Wenzel (12) 109:15 117:19,19,20 117:25 118:16,24 119:8 125:23 162:18 177:1 195:25 Wenzel's (5) 43:25 81:5 118:18 148:15 175:15 weren't (5) 26:25 131:5 162:20 217:9 223:14 whack (1) 242:18 whatsoever (2) 79:11 211:20 whereof (1) 311:19 whipping (1) 219:12 whoa (3) 146:8,8,8 wide (5) 50:9 137:17 223:4 246:2,17	wider (1) 77:21 wife (1) 13:14 William (14) 1:16 2:4 5:6 6:4 77:4 132:11 181:16 244:4 298:2 309:23 310:7 311:11 312:2 313:3 willing (1) 12:3 withdraws (1) 146:24 withhold (1) 126:9 witness (192) 6:3,4 9:23 11:5 21:1 22:3 23:24 24:25 29:13 39:20 40:6,22 41:24 42:10 44:19 47:20 48:11,21 49:15 50:17 54:25 60:3 63:21,24 64:8 68:12 69:14 70:21 72:17 73:1 74:16 75:9,12 76:5 77:13 77:19 78:16,19 79:5 79:21 80:2,19 82:1 83:25 84:16 85:23 89:24 92:3,13 93:14 94:4,18 95:23 96:9 97:1,7 99:2,23 100:6,23 103:14 104:1,20 106:25 109:4,8 111:9,22 112:12,22 114:1 118:15 119:23 120:6,11 122:6 123:13 125:21 126:14 128:8 129:12,17 130:24 134:12,22 139:1 141:21 142:9,23 146:19 147:19 148:20 150:1,15 151:9 152:11 155:13 157:21 159:8 160:23 161:23 162:15 163:4 168:11 169:20,20 170:6 172:17 174:23 176:1,23 178:13 179:8 180:20 182:11 186:3,11	189:25 194:10 202:15 203:14 204:9 206:17 208:3 209:1 212:11 213:7 218:23 223:9 224:19 225:17 226:8 227:2 228:12 229:22 230:16,18 232:23 235:24 237:21 238:4 240:24 241:15 242:23 243:5,22 249:23 251:24 252:9,15,22 253:13 253:14 254:9 259:22 260:11 263:17 267:19,22 268:5 269:10,11 271:1,13,13,17 272:3,15 273:6,15 273:18 275:13 279:24 280:18 282:3 283:2 291:21 293:5,8 294:8 295:10,25 296:10 299:3 303:8 305:25 306:7 310:4 311:11 311:14,19 312:2 witness' (2) 68:11 83:24 witnesses (1) 143:14 woman (1) 11:14 wondering (2) 21:16 300:4 word (12) 21:2 23:25 73:1 87:12 87:15 99:3 102:9 147:18 189:15,24 265:12 272:8 words (7) 53:24 104:21 180:23 181:4 226:16 254:19 262:14 work (26) 8:23 10:21 11:2 18:22 20:8,12 21:24 24:18 28:5,10 31:19 49:22 121:19 135:6,20 215:5 260:6 274:24 275:12,17,18 276:9 282:9 283:10,19 306:8 workers (4) 104:8,10 184:25	187:18 working (4) 12:12 229:15 237:16 305:9 works (1) 24:18 world (2) 85:22 246:3 worry (1) 265:8 worthy (1) 190:21 wouldn't (17) 23:24 27:25 50:18 84:3 110:1 144:1 157:22,23 160:18 161:13 162:15 202:25 224:1 226:21 240:3 264:2 265:17 wound (14) 81:8,8 151:24,25 167:7 170:10 180:8 205:4 220:19 222:6 222:8 231:3,17 314:22 write (4) 196:19 261:9 282:10 305:10 writing (8) 19:7 42:11,12,12 123:14,14 199:25 282:18 written (13) 55:3 61:17,18 62:24 123:7,16 181:20,24 199:6,15,15 245:12 281:5 wrong (4) 30:11 36:10 155:2 194:11 wrote (8) 27:4 31:24 76:15 145:3 163:25 183:13 201:2 279:13	255:23 xylosus (2) 255:23 256:4 <hr/> Y <hr/> Y (4) 176:16,17 178:5,7 Yadin (2) 18:8,10 Yadin/David (1) 18:12 yardstick (2) 42:3,6 yeah (61) 20:22 22:3 23:24 25:21 30:21 35:1,6 39:12,14 40:12,22 41:24 63:23 81:24 83:25 89:11 98:1 112:11,22 118:8 132:22 133:20 136:20 140:16 141:4 144:1,11 146:13 147:19 154:2 162:15 173:13 176:23 181:8,10 185:6 191:17 192:7 193:13 200:20,22 200:22 202:15 207:21,21 215:9 217:9 239:10 242:10,23 243:17 258:13 259:22 261:24 271:17 282:7 288:4 298:9 299:3,17 302:8 year (13) 61:16,19 138:1 144:10,12 201:22 226:6 234:23 235:6 235:9 236:25 284:7 284:8 years (36) 7:17 55:2,11,21 56:9 58:2 105:3 113:5,5 117:21,25 123:6 125:23 136:22,24 152:24 153:1,20 154:2,2,10 155:9 156:22 157:1,13 159:1 162:25 163:23 164:4,5,8 190:2 205:13 234:23 245:11 275:12
---	---	--	--	---

yesterday (1) 47:18 Yup (6) 60:10 132:22 247:24 267:23 279:2 286:19	102:16 107:13,14 110:7,8,11 177:6 210:19 212:15,24 247:18 275:14 286:9 289:2 313:23	46:13 132:13,15 199:20 304:9,13 307:1,4,13,18 308:5 308:16,17,21 309:6 309:8 314:10	164:8,13,19 180:13	2010 (2) 74:20 301:22
Z	10-micron (2) 78:1 293:2	1437 (1) 239:10	197 (2) 314:19,21	2011 (2) 62:23 189:7
zero (3) 124:20 193:10 314:4	10:36 (2) 76:24 77:1	15 (27) 38:16 56:9 58:2 71:22 71:23,25 72:1 73:10 73:15 77:8 88:10,24 92:15 139:16,19,24 140:22 141:8 142:14,20 146:1 147:16 154:2 257:15 275:14 286:9 314:12	1978 (1) 180:17 1980 (1) 153:21 1985 (1) 91:10 1990 (2) 209:7 226:8 1999 (23) 51:12 52:1,22 54:20 56:3 64:19 65:5 68:16 153:23 155:4 156:17 157:11,14 163:24 164:3,10 165:5 166:12 167:22 170:18 181:21,25 313:11	2012 (3) 34:6 47:5,11 2014 (2) 34:15 68:22 2016 (26) 8:17,17,18,18,18,22 9:3,15 12:17 13:18 14:25 15:2 19:2,13 19:23 36:13 37:7,11 37:14,17,24 244:14 260:22 261:12 298:20 315:9
zzt (1) 102:14	100 (1) 289:3 1010 (2) 247:11,23 103 (3) 154:14 166:10 170:19 107 (1) 313:23 11 (11) 8:17 9:2,14 12:17 37:11 63:2 123:19 123:21 125:6 126:25 314:3	1542 (1) 208:8 1543 (2) 216:18 217:2 16 (11) 169:14,16 192:6 256:12,17,23 257:1 257:18 296:15,24 314:14 169 (1) 314:14 17 (10) 13:20 105:3 152:25 163:22 164:4 182:5 182:8,13 307:6 314:17 18 (13) 8:18 15:5 38:8 156:22 157:1,13 162:25 192:2,5 194:15 205:17 206:11 314:18 18-year-old (1) 214:19 182 (1) 314:17 18th (1) 13:20 19 (12) 154:1 155:10 164:4,5 194:10,15 196:24 197:2,4 202:9 205:16 314:19 192 (1) 314:18 1968 (7) 154:23 155:3 158:6	2	2017 (42) 1:18 2:1 5:2,13 7:4,20 8:19,19 15:11 18:23 19:4,8 25:22 32:5 32:11,19,24 33:8 34:15,19 39:16,23 40:9 43:9 57:10 62:11,24 63:2,4,14 64:23 65:8 66:25 107:19 139:14,19 140:22 310:9 311:20 313:14,25 316:23
0	118 (1) 313:20 12 (8) 9:2,14 47:4 125:5 126:18,19,21 314:7 12:06 (2) 132:6,8 12:53 (2) 132:8,11 123 (1) 314:3 124 (1) 182:23 124789 (1) 1:25 126 (1) 314:7 127 (4) 183:18 184:4 187:16 314:8 12885 (2) 1:24 311:24 13 (13) 8:17,22 20:1 22:25 24:7 37:7 38:3,18 127:19,23 247:15 296:23 314:8 132 (1) 314:10 139 (1) 314:12 14 (17)	1544 (1) 208:8 1543 (2) 216:18 217:2 16 (11) 169:14,16 192:6 256:12,17,23 257:1 257:18 296:15,24 314:14 169 (1) 314:14 17 (10) 13:20 105:3 152:25 163:22 164:4 182:5 182:8,13 307:6 314:17 18 (13) 8:18 15:5 38:8 156:22 157:1,13 162:25 192:2,5 194:15 205:17 206:11 314:18 18-year-old (1) 214:19 182 (1) 314:17 18th (1) 13:20 19 (12) 154:1 155:10 164:4,5 194:10,15 196:24 197:2,4 202:9 205:16 314:19 192 (1) 314:18 1968 (7) 154:23 155:3 158:6	2	201 (2) 314:19,21 1978 (1) 180:17 1980 (1) 153:21 1985 (1) 91:10 1990 (2) 209:7 226:8 1999 (23) 51:12 52:1,22 54:20 56:3 64:19 65:5 68:16 153:23 155:4 156:17 157:11,14 163:24 164:3,10 165:5 166:12 167:22 170:18 181:21,25 313:11
0.056 (2) 78:20,22 0.15 (2) 247:19 248:9 0.3 (2) 78:9 80:4 0.5 (7) 48:25 78:9 80:5 89:14 91:5 92:14 247:14 0.5-3.0 (1) 88:23 0.56 (3) 78:8,16,22 0.99 (1) 78:10 001 (1) 78:7 015 (1) 78:8	1	152666 (2) 1:6 5:10 1542 (1) 208:8 1543 (2) 216:18 217:2 16 (11) 169:14,16 192:6 256:12,17,23 257:1 257:18 296:15,24 314:14 169 (1) 314:14 17 (10) 13:20 105:3 152:25 163:22 164:4 182:5 182:8,13 307:6 314:17 18 (13) 8:18 15:5 38:8 156:22 157:1,13 162:25 192:2,5 194:15 205:17 206:11 314:18 18-year-old (1) 214:19 182 (1) 314:17 18th (1) 13:20 19 (12) 154:1 155:10 164:4,5 194:10,15 196:24 197:2,4 202:9 205:16 314:19 192 (1) 314:18 1968 (7) 154:23 155:3 158:6	2 (23) 8:11,14,16 15:9 18:22 25:19 36:9 72:2 77:3 115:2,14 116:16,24 117:2 197:9,11,13 210:20 212:25 216:14 260:22 261:12 313:4 2.9 (1) 78:10 2:01 (2) 181:11,13 2:12 (2) 181:13,16 20 (16) 89:15 158:4,22 162:7 194:15 196:24 197:2,6 199:13,19 205:10,16 231:8 257:15 307:6 314:21 20:11 (1) 315:15 2001 (1) 250:23 2002 (1) 56:8 2003 (1) 153:21 2007 (1) 137:1 2009 (1) 250:23	204 (1) 314:22 21 (13) 8:17 13:18 15:11 37:14 158:4 162:7 204:22,23 209:8 210:14 215:11 237:6 314:22 22 (9) 158:4,4,5 244:11,12 247:11 251:14 290:23 315:3 229 (3) 86:15 91:3 92:1 23 (23) 8:19 15:9 18:23 19:2 19:8 25:22 38:11 39:16,23 40:8 78:9 152:24 190:2 247:1 247:17 248:8 258:2 258:5 261:21,25 278:23 279:1 315:7 24 (7) 14:11 78:10 260:18 260:21 261:20 264:25 315:8 24110 (1)

3:13 244 (1) 315:3 25 (9) 1:18 2:1 5:2,13 14:11 28:2 266:7,10 315:10 250 (1) 43:3 258 (1) 315:7 26 (5) 298:4,7 301:14 313:5 315:12 260 (1) 315:8 266 (1) 315:10 27 (3) 301:10,13 315:14 28 (5) 8:18 19:23 36:12 37:20,24 29 (1) 86:15 29-page (1) 259:12 298 (1) 315:12	301 (1) 315:14 302 (1) 312:6 307 (1) 312:5 31 (16) 7:4,20 19:4,8 32:5,11 32:19,23 33:8 35:2 35:7 40:9 43:9 140:21 141:3 298:24 316 (1) 3:6 32 (1) 7:18 32591 (1) 3:7 35 (1) 50:4 3M (23) 4:12 6:11 106:5 113:5 131:24 132:5 197:15 198:25 199:14 232:19,25 249:10 254:8 268:12 284:16 304:5,11,17,25 308:4,13,20 309:2	46 (3) 261:18 262:4 265:2 47 (6) 78:10 234:24 266:12 267:4 269:11 313:6 48 (2) 270:6 271:16 49 (1) 78:9 497 (1) 54:12 4th (1) 311:20	510(k) (4) 137:13 304:7 308:11 308:13 510(k)s (1) 137:4 55415 (1) 4:7 56 (1) 180:20 57 (2) 155:3 313:12 58 (1) 180:20	8 8 (11) 86:10,12 89:14 114:21 258:6 286:16,18 287:14 288:11 313:4,16 8- (1) 276:19 80 (3) 114:5,19 275:15 800 (1) 275:3 84 (3) 205:13 206:3,4 85 (1) 205:13 86 (2) 205:13 313:16 87 (4) 205:14,15 206:3,4
3 3 (43) 26:5,9 27:7 28:12,20 29:22 32:14 33:3,6 41:9 42:5 46:1 47:3 47:12 72:2 77:21,23 77:23 78:8,14,16,19 79:10 88:9 91:2 92:14 110:8 132:10 139:13,21 143:22 197:9,11,13 215:15 225:18,23 230:11 290:20,21 291:2,7 313:5 3-micron (1) 309:11 3.2 (1) 61:24 3:37 (2) 243:24 244:1 3:50 (1) 244:4 3:51 (1) 244:1 30 (3) 39:1,25 206:4	4 4 (24) 8:18 14:9,25 36:17 37:17 47:7,10,10 72:3 114:8 181:15 197:9,11,13 210:20 212:20,25 215:10 225:22 287:14,17 288:10,11 313:6 4.1 (3) 208:10,22,23 4.6 (1) 208:4 4.9 (3) 78:8,16,19 40 (4) 114:15,17 255:10 256:9 43 (1) 217:1 431 (1) 4:6 4409 (1) 3:20 45 (2) 251:14 290:23	5 5 (33) 48:25 51:6,7 52:1 54:7,13 72:3 77:22 77:22,22,23,24 78:7 78:11 80:5,6 84:5 90:23,24 91:2 102:16 110:8 150:20 153:24 154:14 163:17 166:12 170:18 180:10 197:9,11 244:3 313:10 5- (1) 293:2 5-micron (1) 91:6 5,000 (1) 276:7 5.0 (1) 87:5 5.0-7.0 (2) 86:20 87:25 5.8 (1) 206:15 5:03 (2) 297:22,24 5:15 (1) 298:2 5:16 (1) 297:24 5:33 (1) 309:23 5:35 (1) 310:5 50 (2) 165:5,8 500 (4) 276:21 304:10 308:11 308:24 51 (1) 313:10	6 6 (13) 57:3,4,6 61:2 114:9 197:9,11 298:1,11 309:22 312:5 313:2 313:12 6.9 (1) 206:19 6/29/17 (1) 314:10 60 (5) 168:22,24 301:14 304:16 313:15 63 (1) 309:11 65 (1) 304:16	9 9 (8) 12:19 118:4,6,7 210:18 212:18,18 313:20 9.4 (1) 212:21 9.99 (1) 78:7 9:00 (3) 2:2 5:3,13 90 (1) 275:15 90,000 (2) 25:19 39:15 900 (2) 275:4 276:19 906 (2) 206:23 213:17 914 (2) 230:24 231:7 95 (2) 79:2,5
			7 7 (8) 60:21,22,24 61:4,9,24 61:24 313:15 7,500 (1) 276:7 7.0 (1) 87:5 7.7 (1) 206:6 7/18/10 (1) 315:15 700 (5) 275:2 276:21 304:10 304:16 308:24 70765 (1) 3:14 75 (1) 230:12 77006 (1) 3:21 79 (2) 180:18,19	